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(71) Applicant *(for all designated States except US)*: UNITED STATES SURGICAL CORPORATION [US/US]; 150 Glover Avenue, Norwalk, CT 06856 (US).

(71)(72) Applicants and Inventors: PACALA, Thomas, J. [US/US]; 420 1/2 Heliotrope Avenue, Corona Del Mar, CA 92625 (US). CORREIA, James [US/US]; 10 Barbara Drive, Shelton, CT 06484 (US). PERNA, William, P. [US/US]; 102 Hillside Lane, Monroe, CT 06468 (US). TOSO, Kenneth, E. [US/US]; 32 Old Highway, Wilton, CT 06897 (US). SCHUBERT, Thomas [DE/DE]; Isabellastrasse 45, D-80796 Munich (DE). ERNSTBERGER, Bernhard [DE/DE]; Weisspfennigweg 16, D-81825 Munich (DE). MIDDLECAMP, Markus [DE/DE]; St. Martin Strasse 18a, D-81541 Munich (DE).

(74) Agents: BARRESE, Rocco, S. et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).

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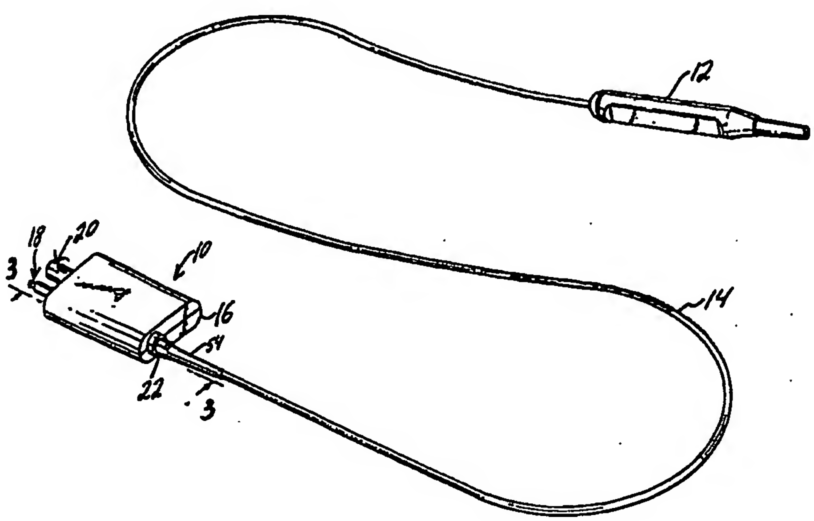

(57) Abstract

Controlled advancement laser ablation devices, and methods are provided for precise ablation of body matter. The laser ablation devices can include a laser energy transmission mechanism such as, for example, an optical fiber (24) mounted for controlled translational longitudinal movement relative to a housing structure (16). A fiber optics coupler (10) is optically coupled to a laser energy generator (60) for transmitting of laser energy via the optical fiber. Controlled advancement mechanisms are provided in engagement with the optical fiber for advancing the fiber at a controlled rate coordinated with the laser energy generator output to ablate body tissue. Various tools for directing the optical fibers are also described. The optical fiber couplers (10), and tools are particularly suitable for use in transmyocardial revascularization (TMR), and angio plasty procedures.

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DEVICES AND METHODS FOR PERFORMING TRANSMYOCARDIAL REVASCULARIZATION

PRIORITY

This application claims priority to a Provisional Application filed on September 24, 1997 by Pacala et al. having Provisional Application Serial No. 60/059,889, the contents of which are incorporated herein by reference.

BACKGROUND

1. Technical Field

The present disclosure relates generally to laser ablation devices for surgical use. More specifically, the present disclosure relates to laser ablation devices having a longitudinally advancing laser energy transmission mechanism to facilitate ablation of body tissue and in particular for performing transmyocardial revascularization (TMR) and angioplasty.

2. Background of the Related Art

One procedure for treating cardiovascular disease is transmyocardial revascularization (TMR), wherein holes are formed in the heart wall to provide alternative blood flow for ischemic heart tissue. This procedure can be done by laser, where laser energy is transmitted from the laser to the heart wall. An optical fiber or bundle of optical fibers can be used to direct laser energy to the heart tissue.

In some TMR procedures, the optical fiber conveying the laser energy is advanced and controlled by hand to form the TMR channel. This manual advancement presents problems in that depth and rate of penetration are difficult to accurately reproduce for the multiple channels necessary in a myocardial revascularization procedure.

In addition, if the advancement rate of the optical fiber is too slow, tissue damage from thermal and acoustic shock can result. On the other hand, if the advancement rate of the fiber is too fast (i.e., faster than the laser ablation rate), the fiber itself, not the laser energy, can mechanically form at least a portion of the hole, which may be undesirable.

Similar problems are present in other cardiovascular procedures such as, for example, laser

angioplasty wherein an optical fiber is inserted and manually advanced into a patient's vasculature to apply laser energy to obstructions and/or restrictions typically caused by plaque build-up. Once again, because the fiber is manually advanced, the rate of advancement of the fiber through the obstruction is generally uncontrolled.

Therefore, there is a need for controlled advancement of a laser fiber in performing both TMR and laser angioplasty.

Minimizing trauma to the patient during surgical procedures is also important. Because laser fibers are flexible, they are particularly suited for percutaneous procedures, wherein the fiber is passed through a patients vasculature, and thorascopic procedures, wherein the fiber accesses the thoracic cavity through relatively small incisions and/or tubes. Both percutaneous and thorascopic procedures are typically less traumatizing to the patient as compared to open procedures.

Therefore, there is also a need for instrumentation and procedures adapted to perform minimally invasive surgery with laser fibers.

SUMMARY

Controlled advancement laser ablation devices and methods are provided for precise ablation of body matter. The laser ablation devices can include a laser energy transmission mechanism such as, for example, an optical fiber, mounted for controlled translational longitudinal movement relative to a housing structure. A fiber optic coupler is optically coupled to a laser energy generator for transmitting of laser energy via the optical fiber. Controlled advancement mechanisms are provided in engagement with the optical fiber for advancing the fiber at a controlled rate coordinated with the laser energy generator output to ablate body tissue. Various tools for directing the optical fibers are also described. The optical fiber couplers and tools are particularly suitable for use in transmyocardial revascularization (TMR) and angioplasty procedures.

BRIEF DESCRIPTION OF THE DRAWINGS

Various preferred embodiments are described herein with references to the drawings:

FIG. 1 is a perspective view of an optical fiber coupler connected to a handpiece via a sheath in accordance with the present disclosure;

FIG. 2 is an exploded perspective view of the optical fiber coupler of FIG. 1;

FIG. 3 is an enlarged cross-sectional view of the proximal end of the optical fiber coupler of FIG. 1;

FIG. 4 is a side cross-sectional view of the plunger mechanism of the optical fiber coupler shown of FIG. 1;

FIG. 5 is a perspective view of a laser generator having an output port adapted to receive the coupler of FIG. 1;

FIGS. 6 and 7 are perspective views of the proximal end of the optical fiber coupler shown in FIG. 1 being optically connected to a laser energy generator;

FIG. 8 is a top partial cut-away view of the optical fiber coupler and laser handpiece shown in FIG. 1 connected to a laser energy generator prior to movement of the optical fiber;

FIG. 9 is similar to FIG. 8, wherein the structure within the laser generator has moved a plunger within the optical fiber coupler to move an optical fiber relative to the laser handpiece;

FIG. 10 is a side view of the distal end of the handpiece in proximity to heart tissue;

FIG. 11 is a side view of the distal end of the optical fiber piercing the epicardium;

FIG. 12 is a side view of the optical fiber extending through the heart tissue to form a channel therein;

FIG. 13 is a side view of the optical fiber being retracted back into the handpiece to reveal the channel formed within the heart tissue;

FIG. 14 is a side cross-sectional view of the optical fiber in proximity to plaque in vasculature;

FIG. 15 is a side cross-sectional view of the optical fiber ablating plaque within the vasculature;

FIG. 16 is a side cross-sectional view of the vasculature showing a clear path therethrough after performing laser angioplasty;

FIG. 17 is a perspective view of an alternative optical fiber coupler connected to a handpiece via a sheath;

FIG. 18 is an exploded perspective view of the optical fiber coupler of FIG. 17;

FIG. 19 is an enlarged cross-sectional view of the proximal end of the optical fiber coupler of FIG. 17;

FIG. 20 is a side cross-sectional view of the plunger mechanism of the optical fiber coupler of FIG. 17;

FIG. 21 is a partial, perspective view of a laser generator having an output port adapted to receive the coupler of FIG. 17;

FIG. 22 is a top partial cut-away view of the optical fiber coupler and laser handpiece shown in FIG. 17 connected to a laser energy generator prior to movement of the optical fiber;

FIG. 23 is similar to FIG. 22, wherein the structure within the laser generator has moved a plunger within the optical fiber coupler to move an optical fiber relative to the laser handpiece;

FIG. 24 is a perspective view of an encoded optical fiber coupler having a magnetic stripe for storing information;

FIG. 25 is an exploded, perspective view of the encoded optical fiber coupler shown in FIG. 24;

FIG. 26 is a perspective view of a control module for receiving the encoded optical fiber coupler and controlling the rate of advancement of the optical fiber within the optical fiber coupler and other parameters;

FIG. 27 is a partial, perspective view of the encoded optical fiber coupler shown in FIG. 24 being optically connected to an optical connector of a laser energy generator where the magnetic stripe aligns with a read/write assembly for reading information stored within the stripe and writing information to the stripe;

FIG. 28 is a top partial cut-away view of the encoded optical fiber coupler shown in FIG. 24 with the plunger mechanism being acted upon by a translation rod of the laser energy generator to advance the optical fiber beyond the distal end of the handpiece;

FIG. 29 is a perspective view of a first alternate embodiment of the encoded optical fiber coupler having a magnetic stripe for storing information;

FIG. 30 is an exploded, perspective view of the encoded optical fiber coupler of FIG. 29;

FIG. 31 is a bottom view of the encoded optical fiber coupler of FIG. 29 showing the magnetic stripe;

FIG. 32 is a perspective view of a control module for receiving the encoded optical fiber coupler of FIG. 29;

FIG. 33 is a partial, perspective view showing the encoded optical fiber coupler of FIG. 30 being optically connected to the control module of FIG. 32;

FIG. 34 is a perspective view of a second alternate embodiment of the encoded optical fiber coupler having an integrated circuit (IC) chip for storing information;

FIG. 35 is a bottom view of the encoded optical fiber coupler of FIG. 34 showing the IC chip;

FIG. 36 is a partial, perspective view showing the coupler of FIG. 34 being optically connected to a control module;

FIG. 37 is a perspective view of a third alternate embodiment of the encoded optical fiber coupler having a bar code for encoding data;

FIG. 38 is a bottom view of the encoded optical fiber coupler of FIG. 37 showing the bar code;

FIG. 39 is a side cut-away view of the bar code being scanned by a bar code reading device within a control module;

FIG. 40 is a perspective view of an alternate TMR laser ablation device;

FIG. 41 is a perspective view of an alternate embodiment of a handle portion of a TMR disposable lasing unit;

FIG. 42 is a side, cross-sectional view of the fiber advancing assembly and the handle portion of the TMR lasing unit shown in FIG. 40;

FIG. 43 is a side, cross-sectional view of the fiber advancing assembly and the handle portion with the fiber extending from a distal end of the handle portion;

FIG. 44 is a side, cross-sectional view of the handle portion shown in FIG. 40 accessing a ventricle through the apex of the heart;

FIG. 45 is a side, cross-sectional view of the apparatus of an optical fiber extending from a distal end of the handle portion shown in FIG. 40 positioned to ablate endocardial tissue;

FIG. 46 is a side, cross-sectional view of the optical fiber piercing the endocardium;

FIG. 47 is a side, cross-sectional view of the optical fiber creating a channel within the heart tissue extending from the endocardium towards an inner surface of the epicardium;

FIG. 48 is a side, cross-sectional view of the optical fiber after having been withdrawn from the heart tissue;

FIG. 49 is a side, cross-sectional view of an alternative embodiment of the handle portion of FIG. 40 having structure for coring the apex of the heart;

FIG. 50 is a side, cross-sectional view of the embodiment of FIG. 49 creating a channel within the heart tissue extending from the endocardium towards an inner surface of the epicardium;

FIG. 51 is a perspective view of an alternate, preferred handpiece suitable for use in TMR procedures;

FIG. 52 is an exploded perspective view of the handpiece of FIG. 51;

FIG. 53 is an elevated cross-sectional view of the handpiece of FIG. 51;

FIG. 54 is a detailed drawing of the proximal end of FIG. 53;

FIG. 55 is a detailed drawing of the articulation control mechanism and associated internal structures of the handpiece shown in FIG. 53;

FIG. 56 is a detailed drawing if the distal end of FIG. 53;

FIG. 57 is an elevated cross-sectional view of the handpiece of FIG. 51 showing movement of the articulation control mechanism;

FIG. 58 is an elevated cross sectional view of the proximal end of the handpiece of FIG. 51 shown with a laser fiber passing therethrough and in a fully articulated position;

FIG. 59 is a detailed drawing of the proximal end of FIG. 58;

FIG. 60 is a detailed drawing of the distal end of FIG. 58;

FIG. 61 is a perspective view of the handpiece of FIG. 51 and a minimally invasive access device;

FIG. 62 is an elevational view in partial cross-section of the instrument of FIG. 51 inserted through a minimally invasive access device disposed in a patient's chest, wherein the distal end of the device is in contact with heart tissue;

FIG. 63 is a detailed drawing of a laser fiber extending from the distal end of the handpiece of FIG. 51, wherein the laser fiber is pressing against heart tissue;

FIG. 64 is a detailed drawing of a laser fiber extending from the distal end of the handpiece of FIG. 51, wherein the laser fiber has penetrated heart tissue; and

FIG. 65 is a perspective view of the handpiece of FIG. 51 being inserted into an incision in a patient's chest to access heart tissue.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

FIG. 1 illustrates a preferred optical fiber coupler shown generally at 10 connected to handpiece 12 via laser fiber sheath 14. Coupler 10 includes a housing 16, a plunger mechanism 18, an optical connector 20, and an opening 22 at a distal end for passage of an optical fiber 24 therethrough. With reference to FIG. 2, optical fiber 24 is disposed within housing 16 with the proximal end secured to nose module 26. Nose module 26 preferably includes a metallic portion 28 and a washer 30. Metallic portion 28 is preferably aluminum and includes conical section 32 and cylindrical section 34. Washer 30 is preferably rubber or a rubber-like material. Optical fiber 24 can protrude slightly from conical section 32 to become optically connected to a laser energy generator.

With continued reference to FIG. 2, plunger mechanism 18 preferably includes plunger 40, cylindrical drum 42, and spring 44. Optical fiber 24 enters cylindrical drum 42 through opening 46 (see FIG. 3). Optical fiber 24 exits the cylindrical drum 42 through a second opening 48 on distal face 50. Optical fiber 24 traverses spring 44 enters sheath 14. An internally threaded bushing 52 is disposed at opening 22 of coupler 10 and threadingly receives sheath 14 (see also FIG. 4). Bushing 52 can be rotated to increase or decrease the effective length of sheath 14 between coupler 10 and handpiece 12. By adjusting the length of sheath 14, the relative distance between coupler 10 and handpiece 12 is adjustable. Because laser fiber 24 is fixed to coupler 10, shortening or lengthening the sheath causes the fiber to move relative to handpiece 12. As such, bushing 52 allows for fine

adjustment of the fiber relative to the handpiece. Similar structures can be provided where the sheath attaches to the proximal end of handpiece 12 (see, also, handpiece 500, below). Flexible support tube 54 surrounds the proximal end of sheath 14 to reduce stress at the interface with coupler 10.

As shown in FIG. 3, optical connector 20 is a female connector preferably having two backward "c" cut-outs 56 for matingly engaging an optical connector 58 of the laser as shown by FIGS. 6 and 7. It is contemplated that fastening mechanisms can be used to further secure coupler 10 with the laser, such as thumb screws. Preferred materials for coupler 10 and related parts include biocompatible plastics, polymers and metals.

Optical fiber coupler 10 can also be provided with a transponder chip, designated as TC in FIGS. 2 and 3. Transponder chip TC is preferably a glass embedded chip having contact recognition capabilities. In one embodiment, a sending and receiving antenna associated with the laser unit can read and process information contained within the chip. Information in the chip can include, for example, sterilization data, laser fiber and coupler information, including serial numbers associated with various parts and the like.

When coupler 10 is optically connected to the laser, laser energy transmission source engages the proximal end of optical fiber 24 to transmit laser energy to optical fiber 24 upon activation of the laser energy. A suitable laser energy generator is shown in FIG. 5 and designated by reference numeral 60. Laser generator 60 includes optical connection port 61 which includes optical connector 58 for connecting coupler 10 to the laser.

Laser 60 further includes a foot operated actuator 62 that activates laser source 36 within the laser when it is depressed. Laser 60 is programmable to suspend energy transmission or movement of a laser fiber, if it is determined, for example, that the optical fiber 24 has sufficiently penetrated body tissue. In this respect, laser 60 can be programmed to control the motors or similar advancing structure within the laser to control the advancement of optical fiber 24 upon actuation of foot operated actuator 62. Other suitable laser energy generators and fiber advancing mechanisms are disclosed herein and in commonly assigned U.S. patent application serial numbers 08/648,638 (filed May 13, 1996) and 08/720,934 (filed October 4, 1996). A mechanism and method for automatically

controlling the longitudinal advancement of a laser fiber is disclosed in commonly assigned U.S. patent application serial number 60/053,309 (filed July 22, 1997).

Laser 60 is shown with a programmable computer 64 having a terminal 66 for storing instructions required to operate an advancing mechanism 68 within the laser for activating plunger mechanism 18 of coupler 10. A toggle button 70 may be provided to switch from an operation mode to a test mode. In a particular test mode, when foot operated actuator 62 is acted upon, optical fiber 24 is moved sequentially from a retracted position, to a predetermined extended position, and back to the retracted position.

With reference to FIG. 8, the advancing mechanism 68 of the laser includes translation rod 72 with proximal end 74 capable of engaging plunger 40 of optical fiber coupler 10 for advancing optical fiber 24 upon activation of the laser. Preferably, rod 72 has a slot configured to receive the proximal end of plunger 40 as coupler 10 is rotated into engagement with the laser. It is contemplated that optical fiber 24 can be a single fiber or an optical fiber bundle or other laser energy transmission mechanism. Most preferably, optical fiber 24 is a bundle of fibers having a collective diameter of about 1.2mm to about 1.6mm.

Controlled longitudinal motion of the optical fiber 24 can be provided by one or more motors and preferably by one or more D.C. motors within the laser to cause translation rod 72, thereby pushing plunger 40 distally to advance optical fiber 24 as further described below. Alternately, stepper motors or other suitable drive mechanisms can be used.

The laser can be either a continuous wave laser or a pulsed, high energy laser; such as, for example, an excimer, Yag, or an alexandrite laser. Preferably, a pulsed high energy xenon chloride excimer laser is used, such as those available from Spectranetics of Colorado Springs, Colorado, or Medolas of Germany.

With reference to FIG. 9, upon activation of foot operated actuator 62, translation rod 72 is advanced distally to engage and push plunger 40. Plunger 40 thus moves cylindrical drum 42 distally against the bias of spring 44, thereby advancing optical fiber 24 through the distal end of handpiece 12. During operation, the surgeon or operator can use a depth selector on laser 60 to select the

desired depth optical fiber 24 will feed into the body tissue. Upon completion of a desired stroke, rod 72 is retracted.

Optical fiber 24 is preferably advanced at a rate that is coordinated with the power level and the frequency of pulsing of the laser. For example, optical fiber 24 can be advanced at a rate of between about 0.125mm/sec (0.005 in/sec) to about 12.7mm/sec (0.5 in/sec) with a laser power level of about 10 mJ/mm^2 to about 60 mJ/mm^2 and a pulsing frequency of about 5 Hz to about 400 Hz. Preferably, the optical fiber is advanced at a rate of about 0.75mm/sec to about 2.0mm/sec with a laser power level of between about 20mJ/mm^2 to about 40 mJ/mm^2 and a pulse frequency of about 30 to about 50Hz. In a most preferred embodiment, the rate of advancement of the optical fiber is no greater than the rate of ablation of tissue in order to minimize mechanical tearing of body tissue by the fiber. Alternatively, if some degree of mechanical tearing is desired, advancing mechanism 68 can be set to advance optical fiber 24 at a rate greater than the ablation rate.

FIGS. 10-13 illustrate the distal end of one embodiment of handpiece 12 in a TMR procedure. Other preferred handpiece embodiments suitable for use with coupler 10 are disclosed, below. With reference to FIG. 10, the distal end of optical fiber 24 is preferably extended about 1-5mm beyond the distal end of handpiece 12. Handpiece 12 is pushed against epicardium 78 and can optionally pierce epicardium 78 as shown by FIG. 11. Foot operated actuator 62 is then actuated to initiate operation of the laser and the advancing mechanism 68 to ablate tissue and advance optical fiber 24 as shown by FIG. 12. FIG. 12 correlates with FIG. 9 which shows translation rod 72 driving plunger 40 to advance optical fiber 24.

With reference to FIG. 13, the distal end of optical fiber 24 is retracted back into handpiece 12 to reveal channel 80 formed within heart tissue 82 extending from epicardium 78 to myocardium 84. This step entails reversing the operation of advancing mechanism 68 to retract translation rod 72 to cause plunger mechanism 18 to return to its original position as shown by FIG. 8. This will cause optical fiber 24 to move proximally, thereby revealing channel 80 formed within heart tissue 82.

After the surgeon has finished with a particular patient, coupler 10 can be removed laser generator 60 and discarded. The laser and the translation rod 72 are then cleaned and inspected for

the next patient. Optical fiber coupler 10, in combination with the relatively quick and easy to use connection to the laser, provides a convenient and safe method of performing laser surgery.

In an alternate method of performing TMR, it is possible to create channels in the myocardium from within the heart by introducing the optical fiber into the patient's vasculature or through an opposing heart wall and directing the fiber tip to the desired location. In this approach, once the fiber is properly placed, controlled advancement of the optical fiber 24 can be achieved as described above. However, with this approach the optical fiber 24 preferably will not penetrate the epicardium. A particular aapparatus and method of performing TMR from within the heart is described below.

Referring now to FIGS. 14-16, coupler 10 and fiber advancing mechanism 68 can also be used to perform laser angioplasty. During the laser angioplasty procedure, optical fiber 24 is inserted into a blood vessel 86 such that optical fiber 24 is positioned adjacent plaque obstruction 88 (FIG. 14), as is known in the art. Foot operated actuator 62 is actuated to initiate operation of the laser and the fiber advancing mechanism 68 to move fiber 24, in the direction indicated by arrow "A". In this procedure, optical fiber 24 ablates plaque 88 to produce channel 90 through the plaque obstruction 88.

As discussed above, the rate of advancement of optical fiber 24 and the power level and frequency of pulsing of laser energy are coordinated, to form channel 80 through plaque 88. By precisely controlling the rate of advancement of optical fiber 24, the user can ensure that plaque 88 is truly ablated by the laser energy and not just pushed aside. Ablation/removal of plaque 88 may reduce the likelihood of or delay restenosis as compared to mere mechanical manipulation of plaque 88.

An alternative optical fiber coupler will now be described with reference to FIGS. 17-23. FIG. 17 illustrates the alternative optical fiber coupler shown generally at 100 connected to handpiece 102 via laser fiber sheath 104. Coupler 100 includes a housing 106, a plunger mechanism 108, an optical connector 110, and an opening 112 at a distal end for passage of an optical fiber 114 therethrough. With reference to FIG. 18, optical fiber 114 is disposed within housing 106 with the

proximal end traversing a first opening 116, a locking ring 118 disposed within compartment 120, and a second opening 122. Locking ring 118 firmly holds the proximal end of optical fiber 114 in the center of optical connector 110. Locking ring 118 is preferably made from rubber or a rubber-like material. Optical fiber 114 protrudes slightly from a cone 123 to become optically connected to a laser.

With continued reference to FIG. 18, plunger mechanism 108 preferably includes plunger 124, cylindrical drum 126, and spring 128. Optical fiber 114 enters cylindrical drum 126 through opening 130 (see also FIG. 20). Optical fiber 114 exits the cylindrical drum 126 through another opening 132 on distal face 134. Optical fiber 114 traverses spring 128 and enters sheath 104. An internally threaded bushing 136 is disposed at opening 112 of coupler 100 and threadingly receives sheath 104. Bushing 136 can be rotated to increase or decrease the effective length of sheath 104 between coupler 100 and handpiece 102. By adjusting the length of sheath 104, the relative distance between coupler 100 and handpiece 102 is adjustable. Because optical fiber 114 is fixed to coupler 100, shortening or lengthening sheath 104 causes fiber 114 to move relative to handpiece 102. As such, bushing 136 allows for fine adjustment of fiber 114 relative to handpiece 102. Similar structures can be provided where sheath 104 attaches to the proximal end of handpiece 102. Flexible support tube 138 surrounds the proximal end of sheath 104 to reduce stress at the interface with coupler 100.

Optical connector 110 is a female connector similar to optical connector 20 shown by FIGS. 6 and 7 for optical fiber coupler 10. Optical connector 110 includes two backward "c" cut-outs 140 for matingly engaging an optical connector 142 of the laser as shown by FIG. 19. It is contemplated that fastening mechanisms can be used to further secure coupler 100 with the laser, such as thumb screws. Optical connector 110 and locking ring 118 prevent torque forces from adversely misaligning the optical fiber 114 and the laser output. Preferred materials for coupler 100 and related parts include biocompatible plastics, polymers and metals.

Optical fiber coupler 100 can also be provided with a transponder chip, designated as TC in FIG. 18. As indicated above, transponder chip TC is preferably a glass embedded chip having

contact recognition capabilities. A sending and receiving antenna may be associated with the laser unit to read and process information contained within the chip TC. As with optical fiber coupler 10, information in the chip TC can include, for example, sterilization data, laser fiber and coupler information, including serial numbers associated with various parts and the like.

When coupler 100 is optically connected to the laser, laser energy transmission source engages the proximal end of optical fiber 114 to transmit laser energy to optical fiber 114 upon activation of the laser energy. A partial view of a suitable laser energy generator is shown in FIG. 21 and designated by reference numeral 150. Laser generator 150 includes optical connection port 152 which includes optical connector 142 for connecting coupler 100 to the laser. Laser generator 150 further includes, as described with respect to laser generator 60 above, a foot operated actuator (not shown) that activates laser source 153 (FIG. 19) within the laser when it is depressed. Laser 150 is programmable to suspend energy transmission or movement of a laser fiber, if it is determined, for example, by the optical fiber 114 has sufficiently penetrated body tissue. In this respect, laser 150 can be programmed to control the motors or similar advancing structure within the laser to control the advancement of the optical fiber 114 upon actuation of foot operated actuator. Other suitable laser energy generators and fiber advancing mechanisms are disclosed herein and in commonly assigned U.S. patent application serial numbers 08/648,638 (filed May 13, 1996) and 08/720,934 (filed October 4, 1996). A mechanism and method for automatically controlling the longitudinal advancement of a laser fiber is disclosed in commonly assigned U.S. patent application serial number 60/053,309 (filed July 22, 1997).

Laser 150 is shown with a programmable computer 154 having a terminal 156 for storing instructions required to operate an advancing mechanism 158 within the laser for activating the plunger mechanism 108 of coupler 100. A toggle button 160 may be provided to switch from an operation mode to a test mode. In a particular test mode, when foot operated actuator is acted upon, optical fiber 114 is moved sequentially from a retracted position, to a predetermined extended position, and back to the retracted position.

With reference to FIG. 22, the advancing mechanism 158 of the laser includes translation rod

162 with proximal end 164 capable of engaging plunger 124 of optical fiber coupler 100 for advancing optical fiber 114 upon activation of the laser. Preferably, rod 162 has a slot configured to receive the proximal end of plunger 124 as coupler 100 is rotated into engagement with the laser. It is contemplated that optical fiber 114 can be a single fiber or an optical fiber bundle or other laser energy transmission mechanism. Most preferably, optical fiber 114 is a bundle of fibers having a collective diameter of about 1.2mm to about 1.6mm.

Controlled longitudinal motion of the optical fiber 114 can be provided by one or more motors and preferably by one or more D.C. motors within the laser to distally move translation rod 162, thereby pushing plunger 124 distally to advance optical fiber 114 as further described below. Alternately, stepper motors or other suitable drive mechanisms can be used.

The laser can be either a continuous wave laser or a pulsed, high energy laser, such as, for example, an excimer, Yag, or an alexandrite laser. Preferably, a pulsed high energy xenon chloride excimer laser is used, such as those available from Spectranetics of Colorado Springs, Colorado or Medolas of Germany.

With reference to FIG. 23, upon activation of foot operated actuator, translation rod 162 is advanced distally to engage and push plunger 124. Plunger 124 thus moves cylindrical drum 42 distally against the bias of spring 128, thereby advancing optical fiber 114 through the distal end of handpiece 102. During operation, the surgeon or operator can use a depth selector on laser 150 to select the desired depth optical fiber 114 will feed into the body tissue. Upon completion of a desired stroke, rod 162 is retracted.

Optical fiber 114 is preferably advanced at a rate that is coordinated with the power level and the frequency of pulsing of the laser. For example, as with optical fiber 24, optical fiber 114 can be advanced at a rate of between about 0.5mm/sec (0.02 in/sec) to about 12.7mm/sec (0.5 in/sec) with a laser power level of about 10 mJ/mm^2 to about 60 mJ/mm^2 and a pulsing frequency of about 5 Hz to about 400 Hz. Preferably, the optical fiber 114 is advanced at a rate of about 0.75mm/sec to about 2.0mm/sec with a laser power level of between about $20mJ/mm^2$ to about $40mJ/mm^2$ and a pulse frequency of about 30 to about 50Hz. In a most preferred embodiment, the rate of advancement of

the optical fiber 114 is no greater than the rate of ablation of tissue in order to minimize mechanical tearing of body tissue by the fiber. Alternatively, if some degree of mechanical tearing is desired, the advancing mechanism 158 can be set to advance the optical fiber 114 at a rate greater than the ablation rate.

Reference is to be made to the operation of optical fiber coupler 10 in conjunction with FIGS. 10-13 for understanding the operation of optical fiber coupler 100 in performing a TMR procedure. In an alternate method of performing TMR, it is possible to create channels in the myocardium from within the heart by introducing the optical fiber into the patient's vasculature or through an opposing heart wall and directing the fiber tip to the desired location. In this approach, once the fiber is properly placed, controlled advancement of the optical fiber 114 can be achieved as described above. However, with this approach the optical fiber 114 preferably will not penetrate the epicardium.

Reference can also be made to the description provided for optical fiber coupler 10 in conjunction with FIGS. 14-16 for understanding the operation of optical fiber coupler 100 in performing laser angioplasty. During the performance of a TMR or a laser angioplasty procedure, optical connector 110 and locking ring 118 prevent pull and torque forces from adversely misaligning the optical fiber 114 and the laser output to maintain approximately 100% transmission of the laser energy outputted from laser generator 150 through optical fiber 114. Locking ring 118 embedded and tightly secured within the molding of housing 106 functions to firmly hold optical fiber 114 in position and prevents pull and/or torque forces from misaligning fiber 114 from laser source 153. It is contemplated that other kinds of locking structure, besides a locking ring, can be used to prevent pull and/or torque forces from misaligning fiber 114 from laser source 153.

FIGS. 24-39 illustrate various embodiments of encoded optical fiber couplers for storing data relating to the coupler, such as the manufacturing date of the optical fiber housed within the coupler; the last time the optical fiber was used and sterilized; and other information, such as which surgeons have used the optical fiber and for what type of medical procedure; and statistical power information, for example, the total average and mean intensity of the laser energy transmitted therethrough. Additional information which may be encoded by various electronic mechanisms to an electronic

readable device of the coupler include the fiber size, lot number, and other distinguishing characteristics of the optical fiber. Such information is suitable for determining if the optical fiber is appropriate for a particular patient and for replacing the optical fiber with an identical fiber when it becomes damaged. The encoded optical fiber couplers described below are particularly suitable for performing TMR.

In other cardiovascular procedures such as, for example, laser angioplasty wherein an optical fiber is inserted and advanced into a patient's vasculature to apply laser energy to obstructions and/or restrictions typically caused by plaque build-up, the surgeon generally needs to know information relating to the optical fiber as well. Therefore, the encoded optical fiber couplers described below are also contemplated for other cardiovascular procedures besides TMR.

The encoded optical fiber coupler designated generally by reference numeral 200 in FIG. 24 is similar to the optical fiber coupler described above with reference to FIGS. 1-16. Therefore, the same reference numerals are used to describe the various components of encoded optical fiber coupler 200 and its corresponding control module (FIG. 26). In addition, it is contemplated that the optical fiber coupler described above in conjunction with FIGS. 17-23 can be modified to include the encoding mechanisms described hereinbelow.

With continued reference to FIG. 24, coupler 200 is connected to a handpiece 12 via a sheath 14. Encoded optical fiber coupler 200 includes a housing 16, a plunger mechanism 18, an optical connector 20, and a magnetic stripe 202 at a top surface 23 of the housing 16 for storing information relating to an optical fiber 24 housed within the housing 16.

With reference to FIG. 25, the components of coupler 200 are shown. Reference is to be made to the description provided above with respect to coupler 10 in conjunction with FIG. 2, for an understanding of how the components are assembled and interconnected.

It is contemplated to provide coupler 200 with a transponder chip, designated as TC in FIG. 25. Transponder chip TC is preferably a glass embedded chip having contact recognition capabilities. A sending and receiving antenna may be associated with the laser unit to read and process information contained within the chip TC. Information in the chip TC can include, for example,

sterilization data, laser fiber and coupler information, including serial numbers associated with various parts and the like. It is also contemplated to include the information in the chip TC to the magnetic stripe, such that the chip TC can function as a backup source for the information stored in the magnetic stripe, and vice versa.

When encoded optical fiber coupler 200 is optically connected to a laser energy generator 204 (FIG. 26) which is similar in design and operation to laser energy generator 60, magnetic stripe 202 aligns with a magnetic stripe read/write assembly 206 having a read head (not shown) and a write head (not shown) for reading information stored within stripe 202 and writing information to the stripe 202 relating to the optical fiber 24 (FIG. 27). In particular, stripe read/write assembly 206 is capable of recording magnetic data onto magnetic stripe 202 and of converting magnetic data previously recorded on magnetic stripe 202 into digital information that can be operated upon by internal circuitry to display data on a terminal or to control the operation of coupler 200.

Stripe read/write assembly 206 is designed to encode data onto magnetic stripe 202 in straight line data paths using the edge of housing 16 as a guide so that the data paths are parallel to one edge of the housing 16. Assembly 206 may use friction type, motor driven rollers to drive housing 16 into and out of housing intake enclosure 208 and includes an edge guide 210 (FIG. 28) to maintain the proper orientation of stripe 202 within assembly 206. The reading and writing operations are performed in assembly 206 by driving stripe 202 along the stationary magnetic heads or by driving the heads over stripe 202 by means of a screw shaft once housing 16 is properly inserted within laser energy generator 204.

Additionally, when encoded optical fiber coupler 200 is optically connected to laser energy generator 204, the laser energy source engages the proximal end of optical fiber 24 to transmit laser energy to optical fiber 24. Laser energy is transmitted upon activation of laser energy generator 204 as described above with respect to laser generator 60 shown by FIG. 3.

Laser generator 204 is shown in FIGS. 26 and 27 with a programmable computer 64 having a terminal 66 for storing instructions required to operate advancing mechanism 68 within laser energy generator 204 for activating plunger mechanism 18 of coupler 200. Terminal 66 can also be used to

display information read from stripe 202 or information to be written to stripe 202. Additionally, terminal 66 may display recommendations to the surgeon regarding the specific optical fiber 24 housed within coupler 200, such as the number of additional times laser energy generator 204 can be fired with the specific encoded optical fiber coupler 200 connected thereto.

With reference to FIG. 28, upon activation of foot operated actuator 62, translation rod 72 is advanced distally to engage and push plunger 40. Plunger 40 thus moves cylindrical drum 42 distally thereby advancing optical fiber 24 through the distal end of handpiece 12. During operation, the surgeon or operator can use a depth selector 76 on laser generator 204 to select the desired depth optical fiber 24 will feed into the body tissue.

A first alternate embodiment of the encoded optical fiber coupler will now be described with reference to FIGS. 29-33. Encoded optical fiber coupler is designated generally by reference numeral 220 and includes a housing 222 having three elongated plates 224, 226 and 228 which are held together by screws 230. Plate 226 includes a cut-out portion 232 in alignment with a major bore 234 and a minor bore 236. Optical fiber 238 traverses cut-out portion 232, the major bore 234 and the minor bore 236 and exits housing 222. A magnetic stripe 240 is included on a bottom surface 242 (FIG. 31) of housing 222 for storing and writing information thereto relating to the optical fiber 238.

With reference to FIG. 32, a laser generator is shown designated generally by reference numeral 244. Generator 244 includes a foot operated actuator 246, a laser source 248, and an optical fiber advancement mechanism 250. Foot operated actuator 246 activates fiber advancement mechanism 250 and laser source 248 when it is depressed.

In essence, laser generator 244 operates substantially similar to laser generator 60 other than having a different optical fiber advancement mechanism. For example, just as laser generator 60, laser generator 244 is capable of suspending operation of foot operated actuator 246, if it is determined, for example, by generator 244 that optical fiber 238 has sufficiently penetrated body tissue. In this respect, laser generator 244 can be programmed to control the motors or similar advancing structure of optical fiber advancement mechanism 250 to control the advancement of optical fiber 238 upon actuation of foot operated actuator 246.

Laser generator 244 is shown with a programmable computer 252 having a terminal 254 for storing instructions required to operate advancement mechanism 250. Terminal 254 can also be used to display information read from stripe 240 or information to be written to stripe 240. Additionally, terminal 254 may display recommendations to the surgeon regarding the specific optical fiber 238 housed within coupler 220, such as the number of additional times laser energy generator 244 can be fired with the specific encoded optical fiber coupler 220 connected thereto.

With reference to FIG. 33, laser energy generator 244 includes a slot 256 for insertion of housing 222 therein. Slot 256 includes a read/write assembly 260 for reading information stored within stripe 240 and writing information to stripe 240 relating to optical fiber 238. In particular, stripe read/write assembly 260 is capable of recording magnetic data onto magnetic stripe 240 and of converting magnetic data previously recorded on magnetic stripe 240 into digital information that can be operated upon by internal circuitry to display data on the terminal 254 or to control the operation of coupler 220.

Stripe read/write assembly 260 is designed to encode data onto magnetic stripe 240 in straight line data paths using the edge of housing 222 as a guide so that the data paths are parallel to one edge of housing 222. Assembly 260 may use friction type, motor driven rollers to drive housing 222 into and out of slot 256 and includes edge guides 262 to maintain the proper orientation of stripe 240 within assembly 260. The reading and writing operations are performed in assembly 260 by driving stripe 240 along stationary magnetic heads (not shown) or by driving the heads over stripe 240 by means of a screw shaft once housing 222 is properly inserted within slot 256 and optically connected to laser energy generator 244.

With reference to FIGS. 34-36, a second alternate embodiment of an encoded optical fiber coupler is shown designated generally by reference numeral 300. Coupler 300 includes an integrated circuit (IC) chip 302 on a bottom surface 304 (FIG. 35) of housing 306 for storing information relating to optical fiber 308. Housing 306 is similar to housing 222 of coupler 220 and further includes lateral edge guides 310 for guiding housing 306 along insertion tabs 312 within slot 314 of laser generator 316 (FIG. 36). A conductive surface 318 is included between insertion tabs 312

which engages IC chip 302 to electronically couple IC chip 302 to the inner circuitry of laser generator 316.

When conductive surface 318 is coupled to the IC chip 302, electrical signals from a processor within laser generator 316 can be transmitted to IC chip 302 and vice versa to read and write information to a memory segment of IC chip 302. The memory segment may include a ROM portion and a RAM portion. The ROM portion may store descriptive data of the optical fiber 308, such as fiber size and lot number. The RAM portion may store information which changes according to use, such as how many times the optical fiber 308 was used to transmit laser energy therethrough and the cumulative amount of time that laser energy was transmitted therethrough. Laser generator 316 operates substantially the same as laser generator 244.

FIGS. 37-39 illustrate a third alternate embodiment of an encoded optical fiber coupler designated generally by reference numeral 350 having a bar code 352 (FIG. 38) for storing information indicative of an optical fiber (not shown) traversing sheath 14. It is noted that bar code 352 can be used to represent data which is descriptive of the optical fiber, such as lot number and fiber size. Bar code 352 is included on a bottom surface 356 of housing 358. Bar code 352 encodes data relating to the optical fiber in either or both of the relative widths of the bars 360 and spaces 362, and the relative heights of the bars 360.

As shown by FIG. 39, when housing 358 is connected to laser energy generator 364, bar code 352 faces a bar code reading device 366 for reading the pre-printed bar code 352. Bar code reading device 366 captures an electronic image of bar code 352 and forms a digital representation of the relative widths of the bars 360 and spaces 362 which can be displayed on a terminal and/or provided to a processor within laser generator 364 for subsequent processing.

Charge coupled devices (CCD) or laser based systems are generally used to capture a digital representation of the visual image of the entire bar code 352 and to perform a decode by analyzing the relative heights of the bars 360 and widths of the bars 360 and spaces 362 within the digitized representation as is known in the art.

Encoded optical fiber couplers disclosed and described with reference to FIGS. 24-39, can be

used to perform a TMR procedure as discussed above with respect to optical fiber coupler 10 in conjunction with FIGS. 10-13. Additionally, the encoded optical fiber couplers can be used to perform other cardiovascular procedures, for example, laser angioplasty as discussed above with respect to optical fiber coupler 10 in conjunction with FIGS. 14-16.

It will be understood that various modifications can be made to the encoded optical fiber coupler embodiments disclosed herein. For example, additional devices may be used for storing information relating to the optical fiber besides a magnetic stripe, IC chip or bar code, such as a computer disk or a PCMCIA card which may store data relating to the coupler and not necessarily be attached to the coupler. It is also contemplated to have more than one information storage device and a combination of two or more storage devices for a particular coupler as indicated and shown by FIG. 25.

An alternate embodiment of a TMR device which accesses the heart and forms channels within the heart tissue via an advancing optical fiber will now be described with reference to FIGS. 40-46. Referring to FIG. 40, the illustrative device is designated generally by reference numeral 400. Device 400 preferably includes laser generator 402 having an optical fiber advancing assembly 404, a laser source 405, and a handle portion 406 enclosing therein a portion of optical fiber 408 or any other channel creating member. Optical fiber 408 is housed within sheath 410.

Optical fiber advancing assembly 404 is of the type capable of precisely transmitting longitudinal motion to an optical fiber, optical fiber bundle or other laser energy transmission mechanism as described above with reference to FIG. 32. The controlled longitudinal motion can be provided by one or more motors and preferably by one or more stepper motors. Laser generator 402 may be either a continuous wave laser or a pulsed, high energy laser; such as, for example, an excimer, CO2, Yag, or an alexandrite laser. TMR device 400 is designed to form channels from the endocardium towards an inner surface of the epicardium as discussed below. A difference between advancing assembly 404 and advancing mechanism 68, described above, is that the structure for advancing the fiber is external to the laser generator. As such, lasers such as the Spectranetics CVX-300 excimer laser can be used with advancing assembly 404.

Optical fiber advancing assembly 404 and laser source 405 are operably connected to function simultaneously. For example, by depressing foot actuator (see FIG. 32) of laser generator 402, laser energy is transmitted through optical fiber 408 by laser source 405 while fiber advancing assembly 404 advances optical fiber 408 relative to handle portion 406.

With reference to FIG. 41, handle portion 406 includes housing 412 formed from molded housing half-sections 412a and 412b. Housing 412 includes a proximal, flexible sheath 414 for entry of optical fiber 408, an elongated body 416 preferably having a conical section 418 at one end, and an angled distal section 420 having approximately a 30-45° angle of curvature with respect to the longitudinal axis x-x of housing 412 extending from conical section 418.

Housing half-sections 412a and 412b define a central bore 422, a proximal recess 424, and a distal recess 426. Proximal recess 424 is configured to receive a swivel connector 428 which is fastened to sheath 410. Swivel connector 428 has an annular flange 430 dimensioned to be received within an increased diameter section 432 of proximal recess 424 to permit rotation of housing 416 with respect to sheath 410. Alternately the connection of housing 416 and sheath 410 can be longitudinally adjustable, as described above, with respect to couplers 10 and 100, and below, with respect to handpiece 500.

An optional locator ring 434 is provided at the distal end of angled section 420 for placement against a ventricle wall during a TMR procedure to facilitate proper orientation of handle portion 406 with respect to the heart tissue as shown by FIG. 46. Locator ring 434 can be formed integrally with housing half-sections 412a and 412b or can be removably fastened to angled section 420. A ridged surface 436 is formed on an outer wall of housing half-sections 412a and 412b to facilitate grasping of handle portion 406.

As shown by FIGS. 42 and 43, locator ring 434 preferably has a cylindrical body portion 438 having an annular flange 440 formed at its proximal end. Cylindrical body portion 438 includes a central bore 442 which is aligned with a central opening 444 formed in the distal end of the housing 412 and central bore 446 of angled section 420. Optical fiber 408 is slidably disposed within central bores 422 and 446 such that it can be advanced through opening 444 in housing 412.

During a TMR procedure, advancing assembly 404 is used to advance optical fiber 408 beyond the distal end of angled section 420 of housing 412. Because laser fiber 408 is secured to movable chuck 448 and sheath 410 is secured to stationary chuck 448' (and the proximal end of hand portion 406), movement of chuck 448 by an amount "x" causes optical fiber 408 to move by the same amount relative to handle portion 406 as shown in FIG. 43. The optical fiber, therefore, can be used to ablate the heart tissue to form a channel. Preferred materials for housing 412 and related parts include biocompatible plastics, polymers and metals.

Referring now to the cross sectional illustrations of FIGS. 44-48, a particular TMR procedure in accordance with the present disclosure will be discussed in greater detail. As shown by FIG. 44, during the TMR procedure, the objective is to have the angled distal section 420 enter a ventricle 450 through the heart apex 452 to form one or more channels from the endocardium 454 to an inner surface of the epicardium 456. Entry through the apex can be achieved by incising the apex or through the use of a coring device, a preferred embodiment of which is described below.

With reference to FIGS. 23-26, once the angled distal section 138 is within the ventricle 450, the distal end is brought in contact with the ventricle wall. Optical fiber 408 can either be initially advanced a distance "x," to facilitate placement of fiber 408 within the heart tissue, as shown, or be flush with the distal end of section 420.

As shown in FIG. 47, once optical fiber 408 is brought into contact with the heart tissue at a desired location, the operator initiates laser energy transmission and coordinates advancement of fiber 408 into myocardium 458 to ablate endocardial and myocardial tissue to produce channel 460. Advancement of fiber 408 may occur either continuously as laser energy is outputted, or in discrete steps. Once fiber 408 reaches the inner wall of the epicardium 456, it is withdrawn from the heart tissue, resulting in the channel 460 as shown in FIG. 48.

An alternative preferred embodiment of the angled distal section 420 of the embodiment illustrated in FIG. 40 is illustrated by FIGS. 49 and 50 and designated generally by reference numeral 470. Angled distal section 470 includes structure for penetrating the apex of the heart as well as providing a channel for the laser fiber. Angled distal section 470 includes a mechanical coring

assembly 472 and a channel creating member 474, preferably an optical fiber.

As shown by FIGS. 27-28, the mechanical coring assembly 472 includes a tubular coring member 476 having a coring end 478 which can be formed at an angle "y" with respect to the longitudinal axis of the tubular coring member 476. End 478 can have a plurality of serrations or can be contoured such as, for example, being concave or convex. The TMR procedure using a device having angled distal section 470 is initiated by placing the distal end of the angled distal section 470 in proximity to the apex of the heart. Coring member 476 is rotated and/or linearly advanced in order to core or cut the apex of the heart 452, as illustrated by FIG. 49.

After coring member 476 reaches ventricle 450, coring member 476 can be retracted within angled distal section 470 to prevent accidental piercing or coring within the ventricle 450. The operator can then position the distal end of angled distal section 470 against the endocardium 454 and advance channel creating member 474 to form a channel 480 within the heart tissue as shown by FIG. 50.

An alternate preferred embodiment of a handpiece for guiding an elongate structure is shown in FIGS. 51-65. Handpiece 500 is particularly suited for guiding a laser fiber (or a bundle of laser fibers) to form channels in a heart wall during TMR procedures. The elongate distal end of the handpiece has a controllable, variable curvature and is dimensioned for use in both minimally invasive and in open surgical procedures (see FIGS. 62 and 65, respectively). The distal end of handpiece 500 can also be passed through the apex of the heart to direct laser energy to the inner heart wall. Handpiece 500 can be used with coupler 10 or with any fiber delivery system such as, for example, advancing assembly 404.

Turning to the drawings, with reference to FIGS. 51-56, handpiece 500 includes handle portion 502, distal guiding portion 507 and proximal sheath attachment portion 503. Handle portion 502 is preferably fabricated from glass filled polycarbonate and has first and second handle sections 502A, 502B that can be press fit during assembly. Control knob 512 is longitudinally slidable within slot 513 formed by the assembled handle sections and is secured to the proximal end of articulation control tube 508, which is longitudinally slidable within handle portion 502. Control knob 512 is

preferably fabricated from glass and PTFE filled acetal. Articulation control tube 508 has proximal flange 520 to facilitate engagement with control knob 512 and distal tabs 528 to facilitate engagement with bushing 530 (best seen in FIG. 56). Handle portion 502 further includes stationary inner tube 518, which has proximal flange 520 that is received in recess 522 of the handle portion and distal tabs 524 for engaging fitting 526 (best seen in FIG. 56). Tubes 508, 518 and fitting 526 are preferably made from stainless steel while bushing 530 is preferably made from a plastic or rubber material. Various parts can be coated with a lubricant to reduce friction during operation.

Distal guiding portion 507 includes distal portions of articulation control tube 508, flexible guide tube 510 and tip member 514. As best seen in FIG. 56, fitting 526 secures the proximal end of flexible guide tube 510 to stationary inner tube 518. Articulation control tube 508 has bushing 530 secured at the distal end thereof and is slidably disposed about portions of flexible guide tube 510. Bushing 530 provides a seal between the articulation control tube and the flexible guide tube. Flexible guide tube 510 preferably has tip member 514 secured, such as by crimping, about the distal end thereof. Tip member 514 is preferably made from stainless steel and functions to increase the surface area of the distal tip of flexible guide tube 510 when it comes in contact with tissue, thereby distributing forces and reducing the likelihood of inadvertent tissue damage. Flexible guide tube is preferably fabricated from a shape memory alloy having an unrestricted curvature of about 90°. Suitable shape memory alloys include those fabricated from nickel and titanium and are available through Raychem Corporation, Menlo Park, California. The length of distal guiding portion 507, when straight and measured from the distal end of handle portion 502, is preferably from about 2 to about 6 inches, and most preferably about 4 inches, for open procedures, and from about 5 to about 10 inches, and most preferably about 7.5 inches, for thorascopic procedures.

With reference to FIGS. 52-54, proximal sheath attachment portion 503 includes sheath holder 516 and rear sheath fitting 506. Sheath holder 516 is preferably fabricated from stainless steel, has internal threads 546, flange 546 and a knurled outer surface to frictionally engage inner surface portions of rear sheath fitting 506. Rear sheath fitting is preferably fabricated from polyester or polyurethane, has flange 548 and serves to prevent or reduce the likelihood of damage to

an attached sheath by distributing forces that may occur when handpiece 500 is rotated relative to an attached sheath. Sheath holder 516 and rear sheath fitting 506 are secured to handle portion by disposing their respective flanges, 546 and 548, within recess 522 of the handle portion. A laser fiber sheath 504 can either be longitudinally threaded directly into sheath holder 516 (as described above with respect to coupler 10) or can be attached to an externally threaded sheath adjusting member (552 in FIG. 59) that can be threaded into sheath holder 516.

Operation of handpiece 500 is depicted in FIGS. 53, 57 and 58. In the straight position, FIG. 53, control knob 512 is disposed at the distal end of slot 513. In this position, articulation control tube 508 is disposed about a substantial length of flexible guide tube 510 and, therefore, holds the guide tube straight relative to the longitudinal axis of the instrument. As control knob 512 is retracted in the proximal direction, articulation control tube 508 also moves proximally and unrestricted portions of flexible guide tube 510 are allowed to bend relative to the longitudinal axis of the instrument, as shown in FIG. 57. Complete retraction of control knob 512 in slot 513, FIGS. 51 and 58, allows for maximum articulation of the flexible guide tube. Movement of control knob in the distal direction will decrease the angular displacement of flexible guide tube 510 relative to the longitudinal axis of the instrument. In order to facilitate movement of control knob 512, the knob preferably has a central protrusion 536 and irregular surface portions 538. Control knob 512 also preferably has a resilient ratchet member, 540, configured to interact with recesses 542 in handle portion 502 (FIGS. 52 and 55, for example). Recesses 542 are provided to give the operator tactile sensation as control knob 512 is longitudinally displaced. Most preferably, four recesses are provided and correspond to the degree of articulation of flexible guide tube 510, such as 0, 30, 60 and 90 degrees, relative to the longitudinal axis of handpiece 500. It is also contemplated that articulation control tube 508 can be stationary and flexible guide tube 510 can be secured to control knob 512.

In use, handpiece 500 is attached to a laser fiber sheath, such as sheath 504, having a laser fiber, 505, longitudinally disposed therein. The laser fiber will pass though the proximal portion of handpiece 500, through stationary inner tube 518 and through flexible guide tube 510. The proximal end of fiber will be optically coupled to a laser energy source. Movement of the laser fiber

relative to the sheath and handpiece can be carried out as previously described with respect to either coupler 10 or advancing assembly 404. As such, longitudinal motion of the fiber relative to the handpiece can be controlled to perform a surgical procedure, such as TMR.

During a thorascopic procedure, distal end 507 of handpiece 500 can be passed through an access port, such as cannula assembly 560 in FIGS. 61 and 62. Suitable cannula assemblies are known in the art and generally include a housing 562, an elongate tube extending distally from the housing 564, an insufflation port 566 and a seal 568. Cannula assembly 560 is placed in the body to provide access to a desired location. In the present preferred thorascopic TMR procedure, the distal tip of handpiece 500 is brought into contact with the heart, preferably against the epicardium 600 in the vicinity of the left ventricle 602. Manipulation of control knob 512 can help achieve the desired placement. Once properly located, the operator can activate the laser and the fiber advancing mechanism to cause the laser fiber to create one or more channels 610 in the heart wall. In a most preferred procedure, the laser fiber will be initially advanced slightly past the distal-most portion of flexible guide tube 510. As shown in FIG. 63, this will cause the heart tissue to "tent". Once the laser energy is activated, the tented portions of tissue will move towards the handpiece, FIG. 64, and receive less energy form the laser than the remaining tissue that is ablated. This can help to close off the channel after the laser fiber is removed and, therefore, reduce loss of blood from the heart chamber through the channel.

An open TMR procedure using handpiece 500 is generally shown in FIG. 65. The working end of the instrument is manipulated, as described above, within an open incision to facilitate placement of a laser fiber against the patient's heart. TMR channels are formed as previously described.

It will be understood that various modifications can be made to the embodiments disclosed herein. For example, alternate devices can be used to actuate the proximal advancement of the optical fiber, such as a trigger mechanism associated with the handle portion. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended thereto.

WHAT IS CLAIMED IS:

1. An optical fiber coupler comprising:

a fiber advancing device having a movable member, said fiber advancing device capable of mechanically cooperating with an advancement mechanism of a laser energy generator when said coupler is mounted to said laser energy generator; and

at least one optical fiber having proximal and distal ends, a portion of the fiber defined between the proximal and distal ends being secured to the movable member of the fiber advancing device, said proximal end optically coupled to a laser source within said laser energy generator when said coupler is mounted to said laser energy generator;

wherein upon actuation of said laser energy generator said at least one optical fiber is advanced and laser energy transmitted therethrough.

2. The optical fiber coupler according to Claim 1, wherein said coupler is coupled to a handpiece via a sheath, wherein the distal end of said optical fiber being extendible through the handpiece upon actuation of said laser energy generator.

3. The optical fiber coupler according to Claim 1, wherein said fiber advancing device includes a plunger for pushing said movable member upon actuation of said laser energy generator to advance said at least one optical fiber.

4. A laser ablation device comprising:

a handle portion having proximal and distal openings;

an optical fiber coupler comprising:

a fiber advancing device having a movable member;

at least one optical fiber having proximal and distal ends, the distal end being extendible through the handle portion and a portion of the fiber defined between the proximal and distal ends being secured to the movable member of the fiber advancing device;

a laser energy generator having a fiber advancement mechanism mechanically cooperating with said fiber advancing device when said optical fiber coupler is mounted to said laser energy generator, said laser energy generator further having a laser energy source optically coupled to said proximal end of the at least one optical fiber when said optical fiber coupler is mounted to said laser energy generator; and

an actuator for actuating the fiber advancing device and the laser energy generator for advancing and transmitting laser energy through the at least one optical fiber.

5. The laser ablation device according to Claim 4, wherein said fiber advancing device includes a plunger for pushing said movable member upon actuation of said laser energy generator to advance said at least one optical fiber.

6. A method for performing transmyocardial revascularization comprising the steps of:

creating an opening adjacent an apex of a heart;

advancing a coring member into the myocardium through the opening beyond the depth of the incision to remove myocardial tissue; and

creating at least one channel in the heart tissue by advancing a channel creating device into the heart tissue from the endocardium towards the epicardium.

7. The method according to claim 6, wherein said coring member is a cylindrical tube having a distal coring portion.

8. The method according to claim 6, wherein said step of creating at least one channel in the heart tissue is performed by laser ablation where said channel creating device includes an advancing laser ablation member.

9. The method according to claim 6, wherein said step of creating an opening is

performed by inserting a tubular beveled cutting member adjacent the apex of the heart.

10. A method for performing transmyocardial revascularization comprising the steps of:

creating an opening adjacent an apex of a heart and coring a first channel from the incision to the ventricle;

creating a second channel in the heart extending from the endocardium towards the epicardium using a channel creating device that advances into the heart tissue; and

after forming the second channel, withdrawing the channel creating device from the heart tissue.

11. The method according to claim 10, wherein said step of coring a first channel is performed by a mechanical coring assembly.

12. The method according to claim 10, wherein said channel creating device comprises a lasing device.

13. The method according to claim 11, wherein:

the steps of creating an opening and coring a first channel from the incision to a ventricle are performed substantially contemporaneously by incising the heart tissue via insertion of a beveled cutting end of a tubular cutting member of said mechanical coring assembly a predetermined distance into the myocardium; and

said step of coring a first channel comprises rotatably advancing the tubular cutting member within the heart tissue.

14. The method according to claim 11, wherein said mechanical coring assembly has a linearly advanceable, rotating coring member and wherein said first channel is formed by simultaneously advancing and rotating the coring member at predetermined coordinated rates to core heart tissue.

15. The method according to claim 12, wherein said lasing device includes an optical fiber for transmitting laser energy to ablate myocardial tissue, said optical fiber being advanced through the heart tissue at a rate coordinated with laser energy outputted from said optical fiber to ablate heart tissue and create said second channel.

16. An apparatus for performing transmyocardial revascularization comprising:

a mechanical coring assembly having a tubular coring member for advancing said tubular coring member into the heart tissue adjacent an apex of a heart to core a first channel from the epicardium to a ventricle; and

a channel creating member integrated with said mechanical coring assembly for creating at least one second channel by advancing said channel creating member into the heart tissue from the endocardium towards the epicardium.

17. The apparatus according to claim 16, wherein said tubular coring member is shaped as a beveled, hollow cylinder operative to create an incision and core myocardial tissue upon penetration into the myocardium.

18. The apparatus according to claim 16, wherein said channel creating member comprises at least one optical fiber.

19. The apparatus according to claim 17, wherein said tubular coring member surrounds said channel creating member, said channel creating member capable of advancing through said tubular coring member and emitting laser energy to ablate heart tissue and create said at least one second channel.

20. The apparatus according to claim 16, wherein said apparatus includes means for advancing said channel creating member at a rate coordinated with magnitude of laser energy outputted from said channel creating member to ablate heart tissue and create said at least one second channel.

21. The apparatus according to claim 16, wherein the mechanical coring assembly and channel creating member are housed within a single housing.

22. The apparatus according to claim 21, wherein a distal end of said housing is angled at approximately a 30-45° angle with respect to a longitudinal axis of said housing.

23. A method for performing transmyocardial revascularization comprising the steps of:

creating an opening adjacent an apex of a heart;

advancing a distal end of a handpiece within the opening to enter a ventricle, said handpiece housing a channel creating device therein;

positioning the distal end of the handpiece within the ventricle;

creating at least one channel in the heart tissue by advancing said channel creating device into the heart tissue from the endocardium towards the epicardium.

24. The method according to claim 23, further comprising the step of advancing a coring member into the myocardium through the opening beyond the depth of the incision to remove myocardial tissue simultaneously with the step of advancing the distal end of the handpiece within the opening.

25. The method according to claim 23, wherein said step of creating at least one channel in the heart tissue is performed by laser ablation where said channel creating device includes an advancing laser ablation member.

26. The method according to claim 23, wherein said step of creating an opening is performed by inserting a tubular beveled cutting member adjacent the apex of the heart.

27. A handpiece comprising:

a handle portion having proximal and distal ends, said handle portion including an actuator assembly having an actuator configured to move from a first position to a second position;

an articulation assembly including an articulation control tube having a portion thereof operatively associated with the actuator assembly;

a flexible guide tube extending within a portion of the articulation control tube, wherein movement of the actuator from the first position towards the second position causes the articulation control tube to move proximally to expose at least a portion of the flexible guide tube and movement of the actuator from the second position towards the first position causes the articulation control tube to move distally to conceal said at least a portion of the flexible guide tube.

28. The handpiece according to claim 27, further comprising a laser ablation member having first and second ends, the first end being extendible through a distal end of the flexible guide tube and the second end being configured for optical connection to a laser energy generator.

29. The handpiece according to claim 27, wherein the flexible guide tube is angularly displaced relative to the longitudinal axis of the handpiece as the actuator is moved from the first position towards the second position.

30. The handpiece according to claim 29, wherein movement of the actuator from the second position towards the first position decreases the angular displacement of the flexible guide tube relative to the longitudinal axis of the handpiece.

31. The handpiece according to claim 27, wherein the handpiece is particularly suited for transmyocardial revascularization.

32. The handpiece according to claim 27, wherein the flexible guide tube is manufactured from shape memory alloy.

33. The handpiece according to claim 32, wherein the shape memory alloy has an unrestricted curvature of about 90°.

34. The handpiece according to claim 27, further comprising a tip member having a predetermined surface area and being secured about a distal end of the flexible guide tube to increase the surface area of the distal end of the flexible guide tube.

35. The handpiece according to claim 27, wherein the articulation assembly has a length suitable for performing thorascopic surgical procedures.

36. An optical fiber coupler comprising:

a housing;

a fiber advancing device having a movable member disposed within said housing, said fiber advancing device capable of mechanically cooperating with an advancement mechanism of a laser energy generator when said coupler is mounted to said laser energy generator; and

at least one optical fiber having proximal and distal ends, a portion of the fiber defined between the proximal and distal ends being secured to the movable member of the fiber advancing device, a portion of said proximal end traversing a compartment in said housing and secured thereto by locking structure, said proximal end optically coupled to a laser source within said laser energy generator when said coupler is mounted to said laser energy generator;

wherein upon actuation of said laser energy generator said at least one optical fiber is advanced and laser energy transmitted therethrough.

37. The optical fiber coupler according to Claim 36, wherein said coupler is coupled to a handpiece via a sheath, wherein the distal end of said optical fiber being extendible through the handpiece upon actuation of said laser energy generator.

38. The optical fiber coupler according to Claim 36, wherein said fiber advancing device includes a plunger for pushing said movable member upon actuation of said laser energy generator to advance said at least one optical fiber.

39. The optical fiber coupler according to Claim 36, wherein said locking structure includes a locking ring.

40. The optical fiber coupler according to Claim 36, further comprising a transponder chip having stored information therein.

41. The optical fiber coupler according to Claim 40, wherein said stored information includes at least sterilization data, and laser fiber and coupler information.

42. A laser ablation device comprising:

a handle portion having proximal and distal openings;

an optical fiber coupler comprising:

a housing;

a fiber advancing device having a movable member disposed within said housing;

at least one optical fiber having proximal and distal ends, the distal end being extendible through the handle portion and a portion of the fiber defined between the proximal and distal ends being secured to the movable member of the fiber advancing device, a portion of said proximal end traversing a compartment in said housing and secured thereto by locking structure;

a laser energy generator having a fiber advancement mechanism mechanically cooperating with said fiber advancing device when said optical fiber coupler is mounted to said laser energy generator, said laser energy generator further having a laser energy source optically coupled to said proximal end of the at least one optical fiber when said optical fiber coupler is mounted to said laser energy generator; and

an actuator for actuating the fiber advancing device and the laser energy generator for advancing and transmitting laser energy through the at least one optical fiber.

43. The laser ablation device according to Claim 42, wherein said fiber advancing device includes a plunger for pushing said movable member upon actuation of said laser energy generator to advance said at least one optical fiber.

44. The optical fiber coupler according to Claim 42, wherein said locking structure includes a locking ring.

45. The optical fiber coupler according to Claim 42, further comprising a transponder chip having stored information therein.

46. The optical fiber coupler according to Claim 45, wherein said stored information includes at least sterilization data, and laser fiber and coupler information.

47. An optical fiber coupler comprising:

at least one optical fiber having proximal and distal ends, said proximal end optically coupled to a laser source within a laser energy generator when said coupler is mounted to said laser energy generator; and

a storage device for storing data relating to said at least one optical fiber cooperating with a data processing device when said coupler is mounted to said laser energy generator.

48. The optical fiber coupler according to Claim 47, wherein said storage device is an integrated circuit having at least one data storage segment.

49. The optical fiber coupler according to Claim 47, wherein said storage device is a magnetic stripe.

50. The optical fiber coupler according to Claim 47, wherein said storage device is a bar code.

51. An optical fiber coupler comprising:

a fiber advancing device having a movable member, said fiber advancing device capable of mechanically cooperating with an advancement mechanism of a laser energy generator when said coupler is mounted to said laser energy generator;

at least one optical fiber having proximal and distal ends, a portion of the fiber defined between the proximal and distal ends being secured to the movable member of the fiber advancing device, said proximal end optically coupled to a laser source within said laser energy generator when said coupler is mounted to said laser energy generator; and

a storage device for storing data relating to said at least one optical fiber cooperating with a data read/write device when said coupler is mounted to said laser energy generator;

wherein upon actuation of said laser energy generator said at least one optical fiber is advanced and laser energy transmitted therethrough.

52. The optical fiber coupler according to Claim 51, wherein said storage device is an integrated circuit having at least one data storage segment.

53. The optical fiber coupler according to Claim 51, wherein said storage device is a magnetic stripe.

54. The optical fiber coupler according to Claim 51, wherein said storage device is a bar code.

55. The optical fiber coupler according to Claim 51, wherein said coupler is coupled to a handpiece via a sheath, wherein the distal end of said optical fiber being extendible through the handpiece upon actuation of said laser energy generator.

56. The optical fiber coupler according to Claim 51, wherein said fiber advancing device includes a plunger for pushing said movable member upon actuation of said laser energy generator to advance said at least one optical fiber.

57. A laser ablation device comprising:

a handle portion having proximal and distal openings;

an optical fiber coupler comprising:

a fiber advancing device having a movable member;

at least one optical fiber having proximal and distal ends, the distal end being extendible through the handle portion and a portion of the fiber defined between the proximal and distal ends being secured to the movable member of the fiber advancing device; and

a storage device for storing data relating to said at least one optical fiber cooperating with a data read/write device when said coupler is mounted to said laser energy generator;

a laser energy generator having a fiber advancement mechanism mechanically cooperating with said fiber advancing device when said encoded optical fiber coupler is mounted to said laser energy generator, said laser energy generator further having a laser energy source optically coupled to said proximal end of the at least one optical fiber when said encoded optical fiber coupler is mounted to said laser energy generator; and

an actuator for actuating the fiber advancing device and the laser energy generator for advancing and transmitting laser energy through the at least one optical fiber.

58. The laser ablation device according to Claim 57, wherein said storage device is an integrated circuit having at least one data storage segment.

59. The laser ablation device according to Claim 57, wherein said storage device is a magnetic stripe.

60. The laser ablation device according to Claim 57, wherein said storage device is a bar code.

61. The laser ablation device according to Claim 57, wherein said fiber advancing device includes a plunger for pushing said movable member upon actuation of said laser energy generator to advance said at least one optical fiber.

62. An optical fiber coupler comprising:

at least one optical fiber having proximal and distal ends, said proximal end optically coupled to a laser source within a laser energy generator when said coupler is mounted to said laser energy generator; and

a transponder chip for storing, transmitting and receiving data relating to said at least one optical fiber.

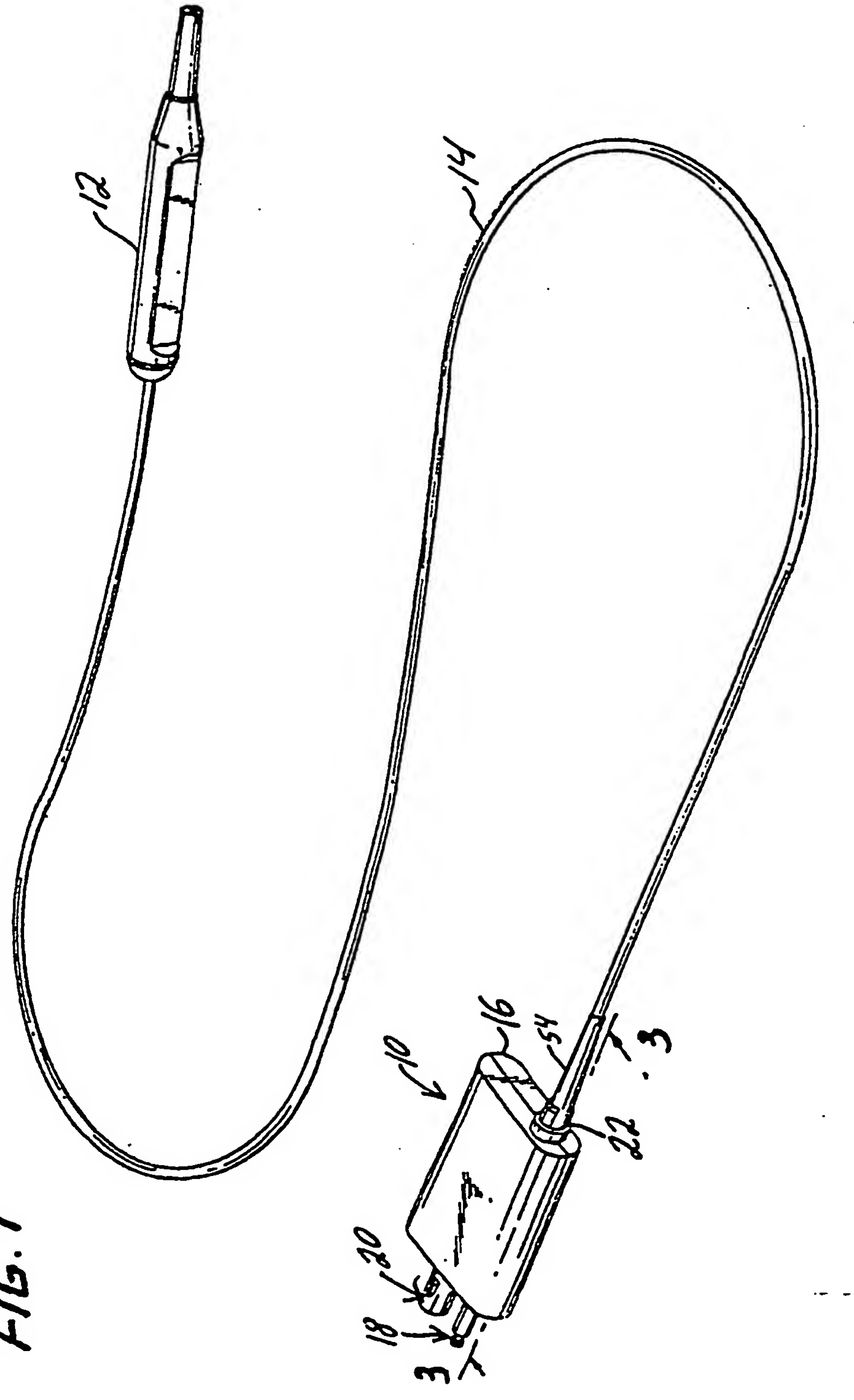
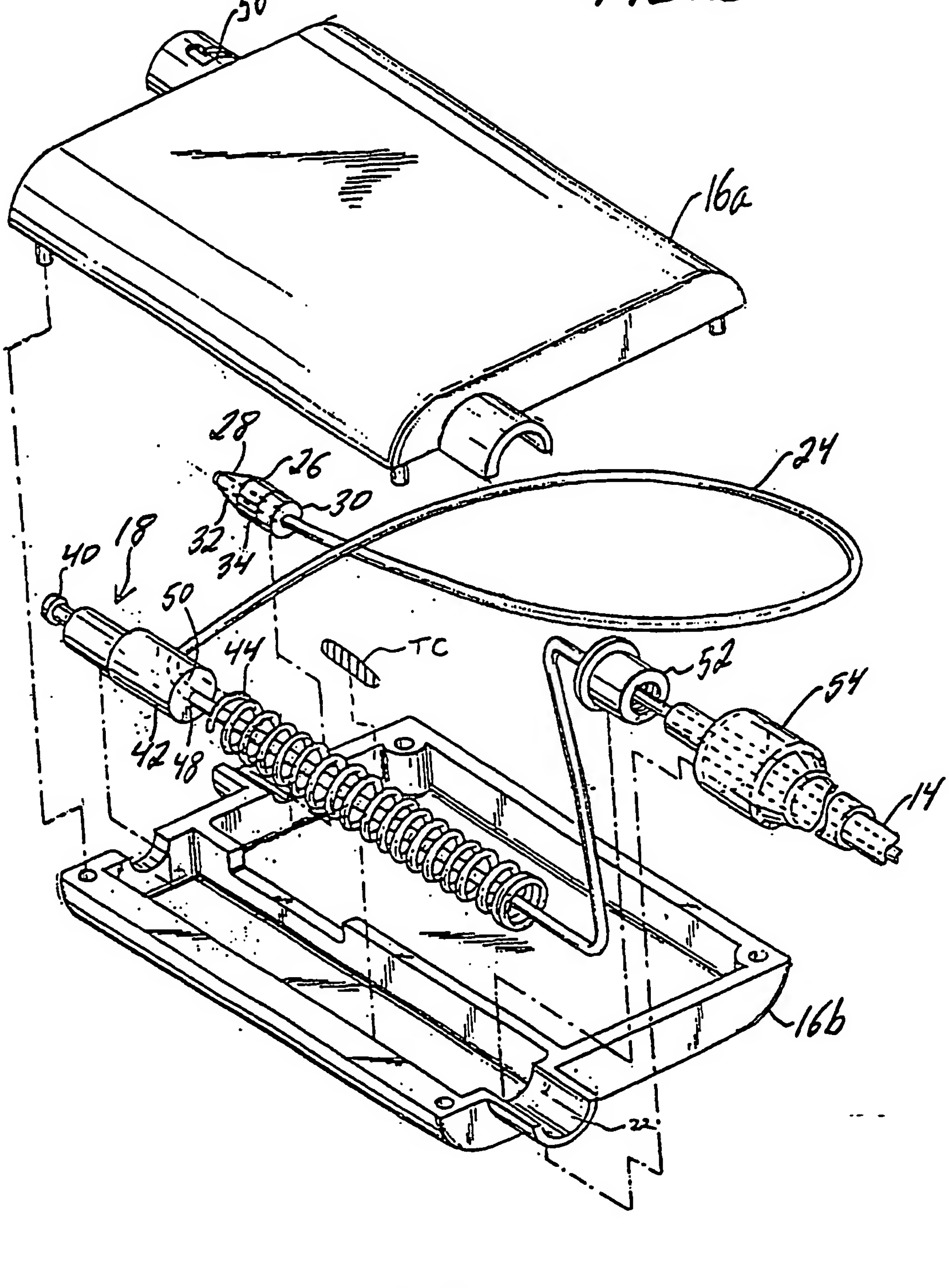


FIG. 1

FIG. 2



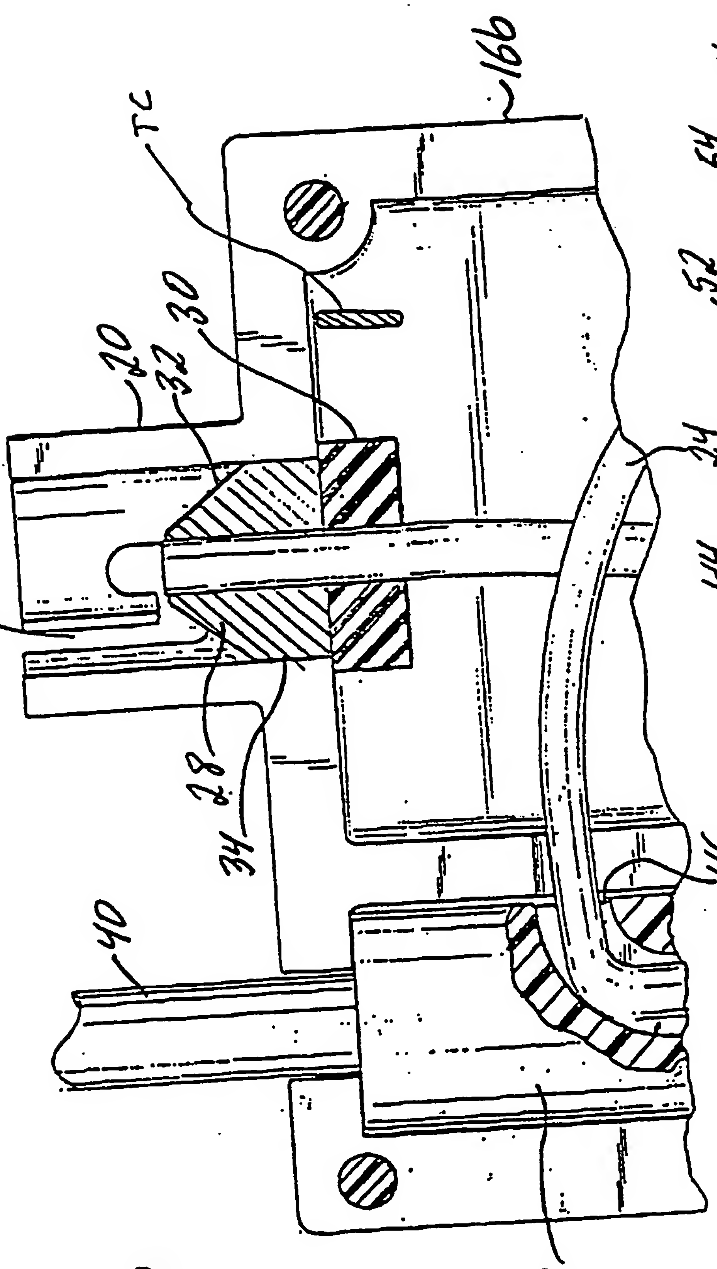


FIG.3

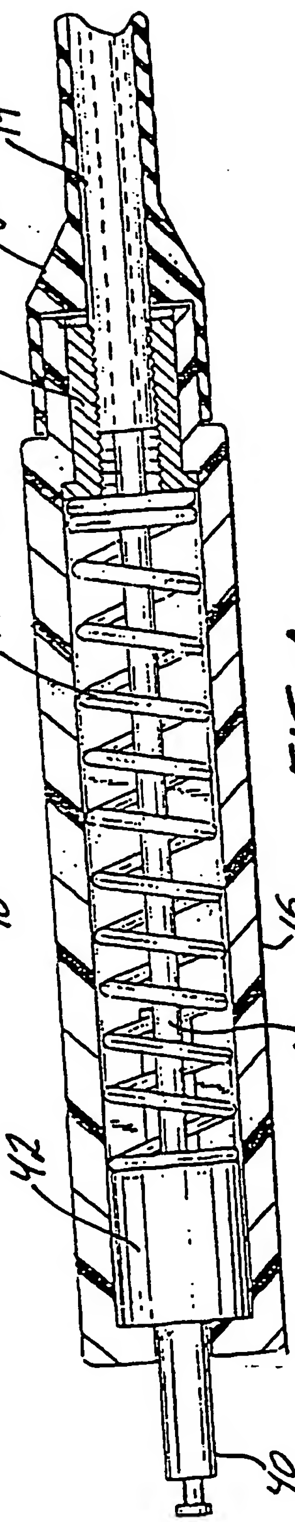


FIG.4

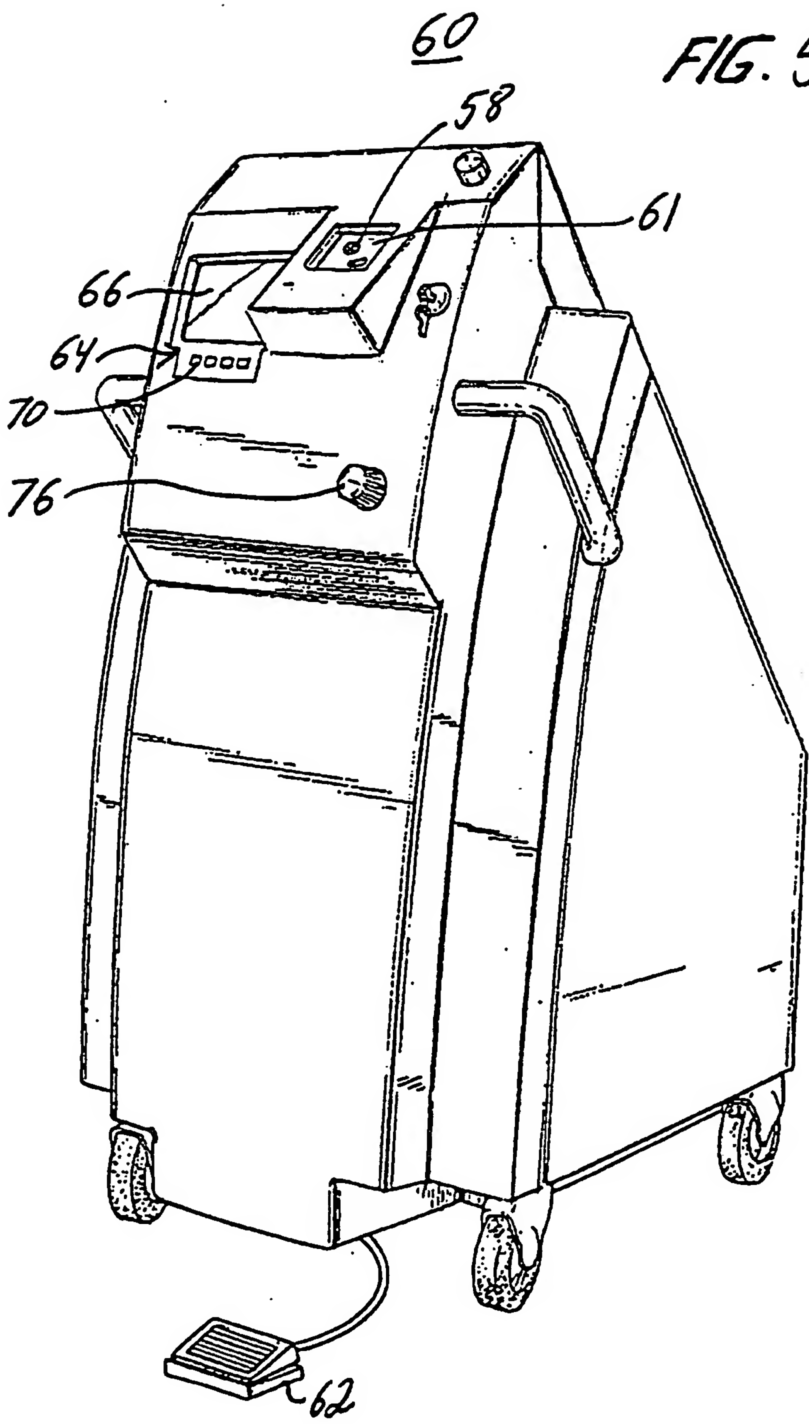


FIG. 5

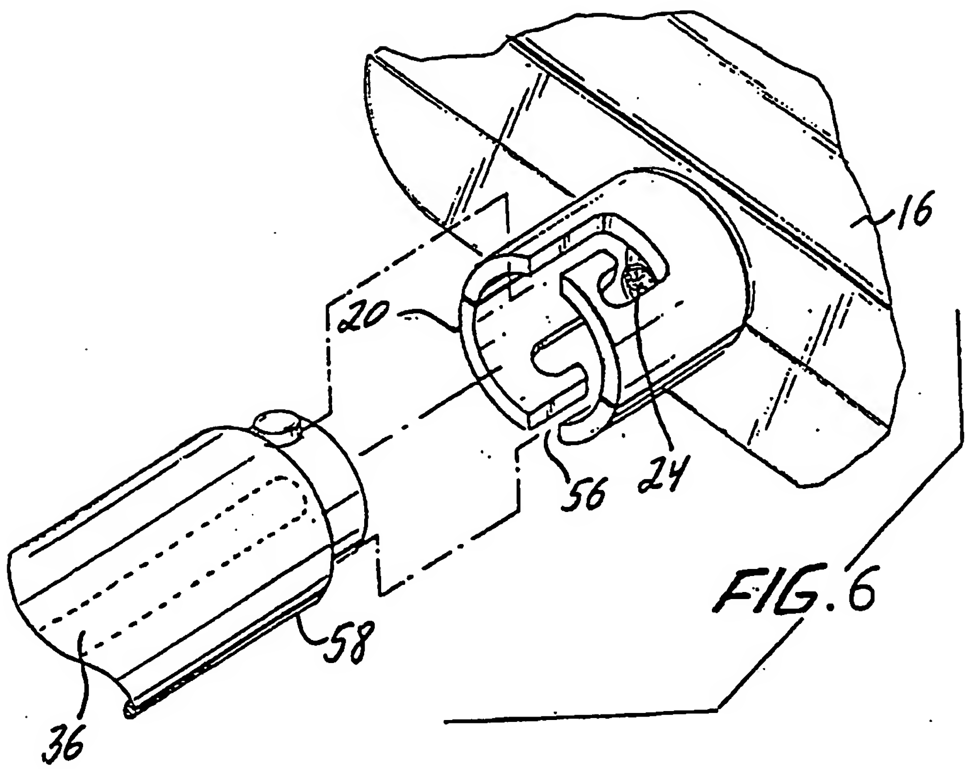


FIG. 6

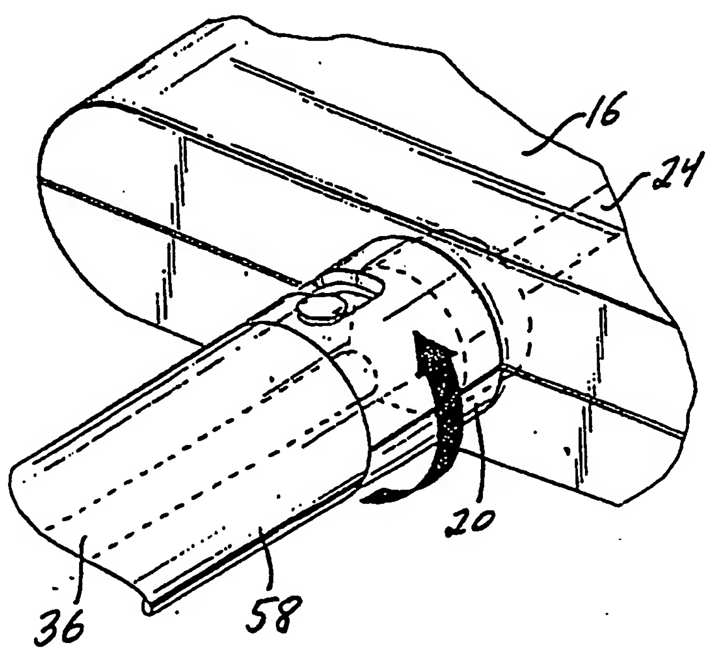
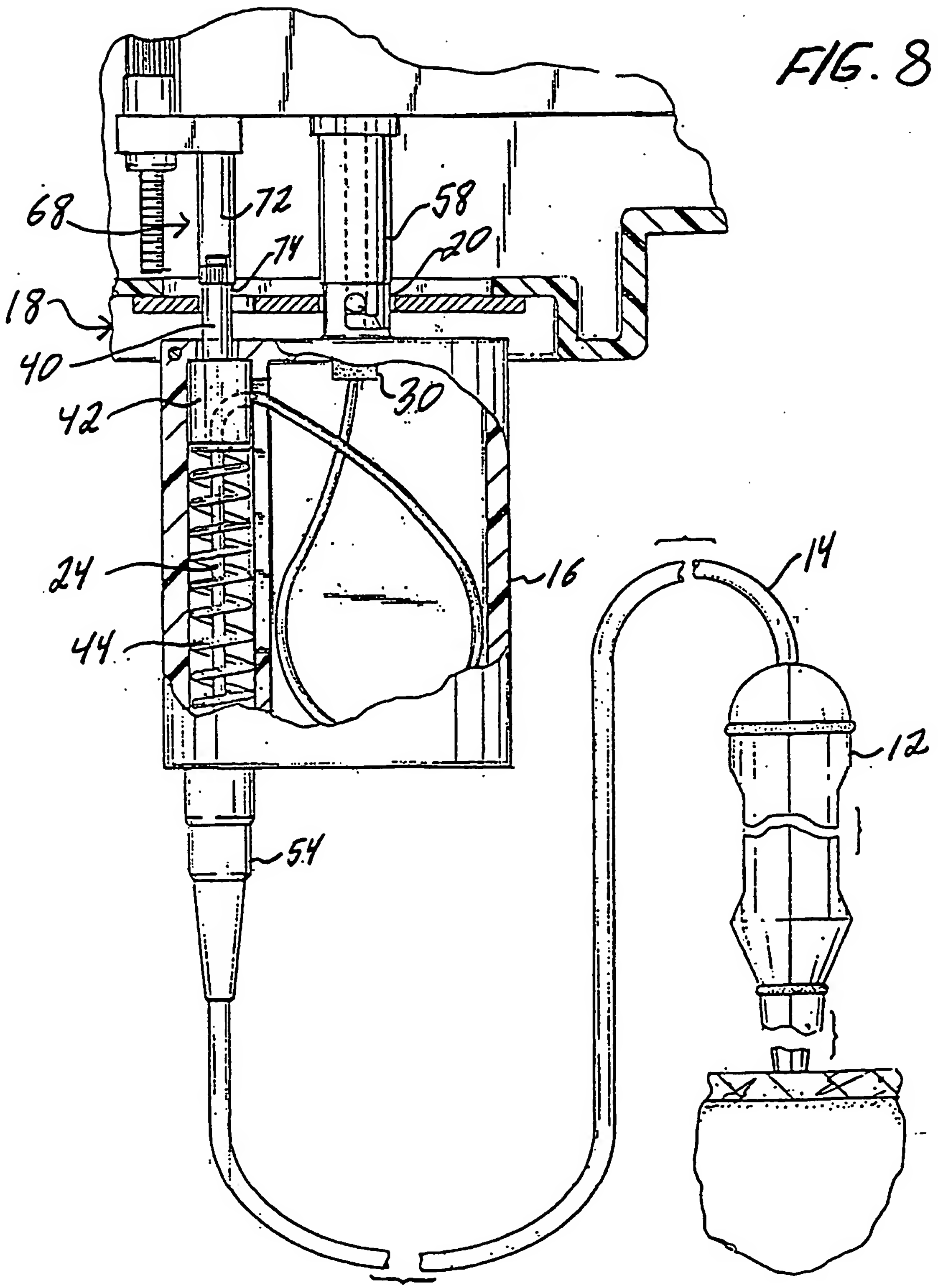


FIG. 7

FIG. 8



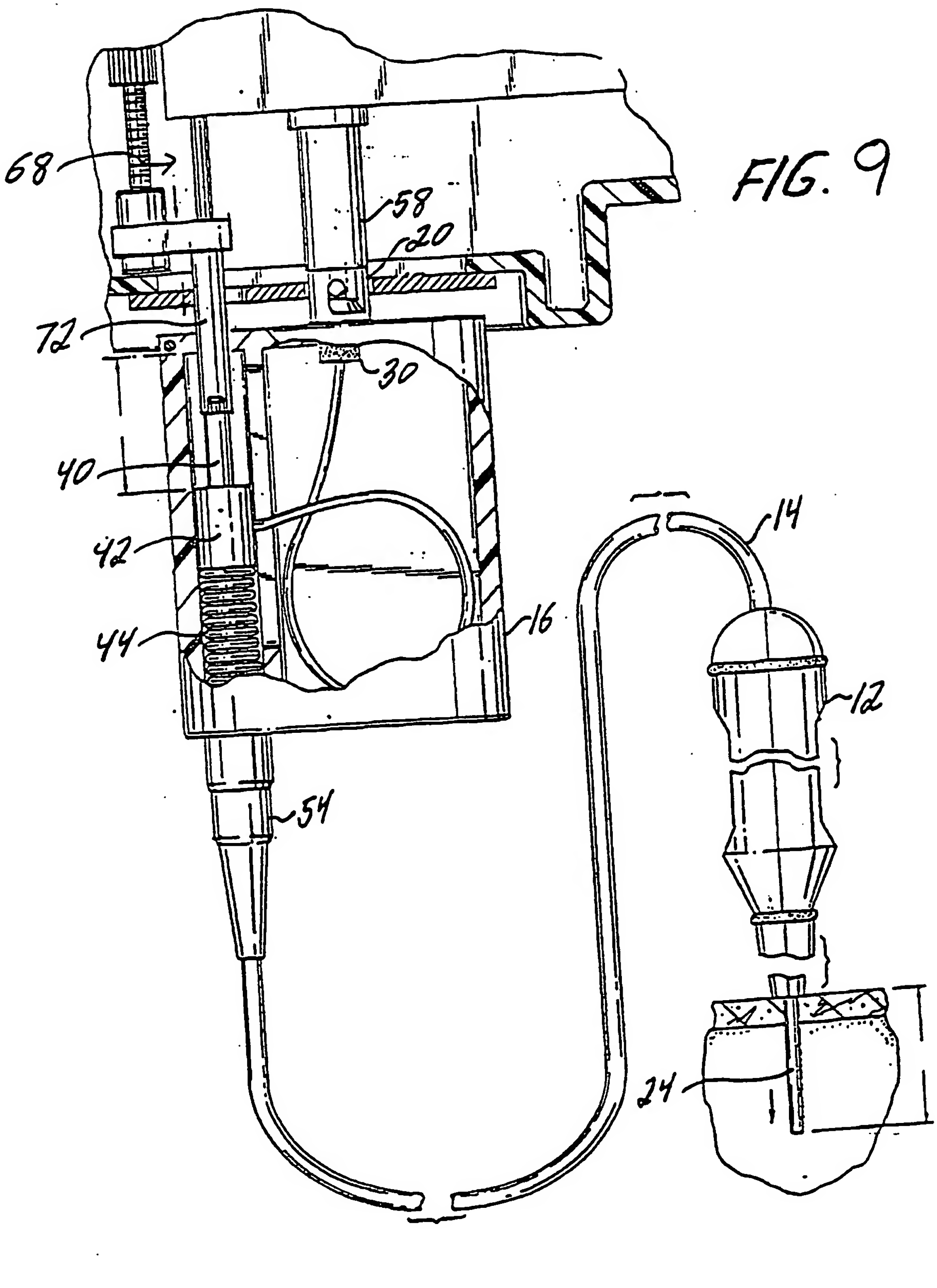


FIG. 9

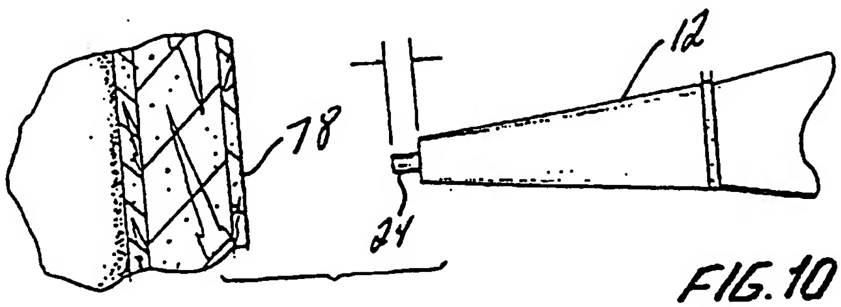


FIG. 10

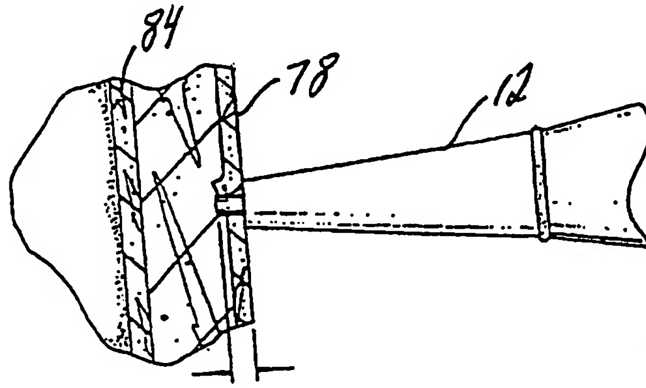


FIG. 11

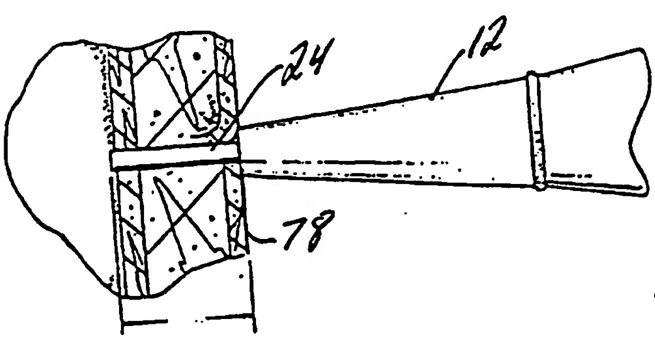


FIG. 12

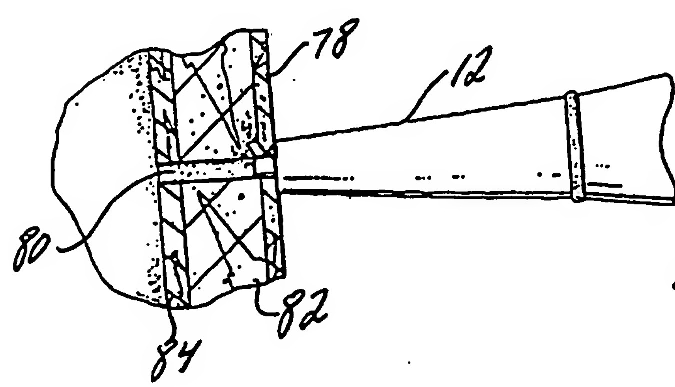


FIG. 13

FIG. 14

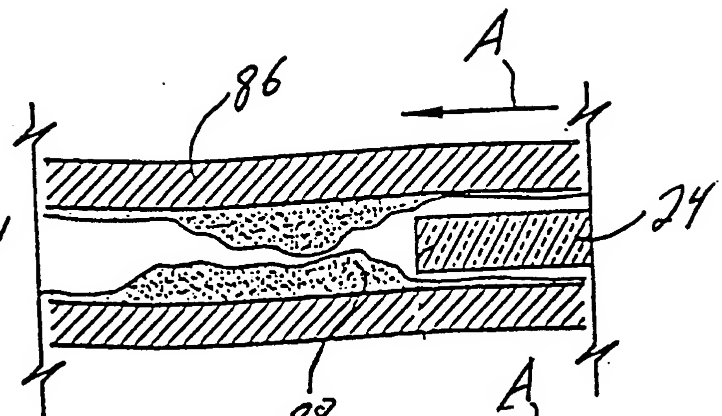


FIG. 15

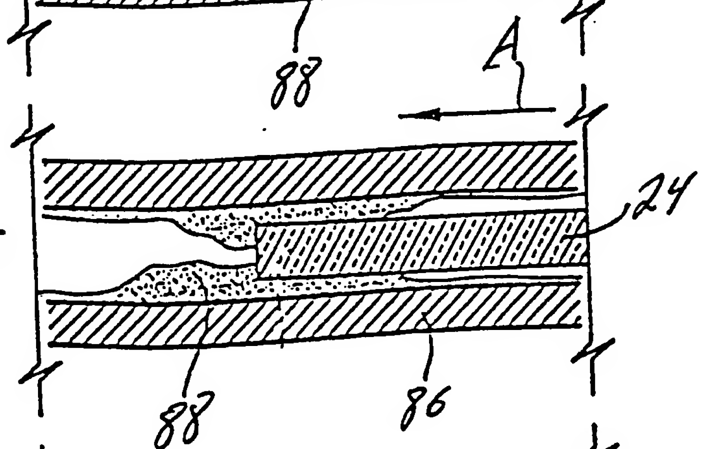


FIG. 16

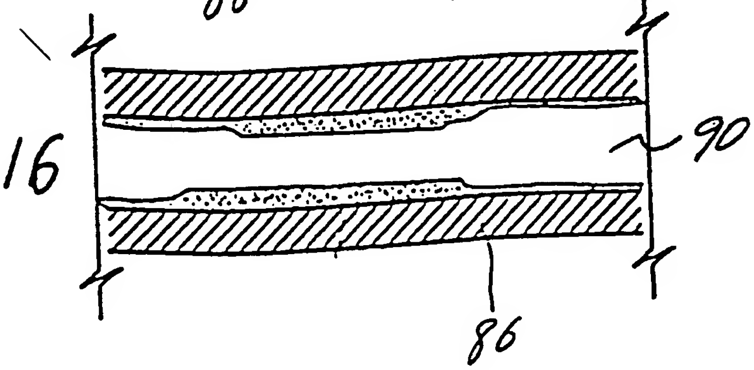


FIG. 17

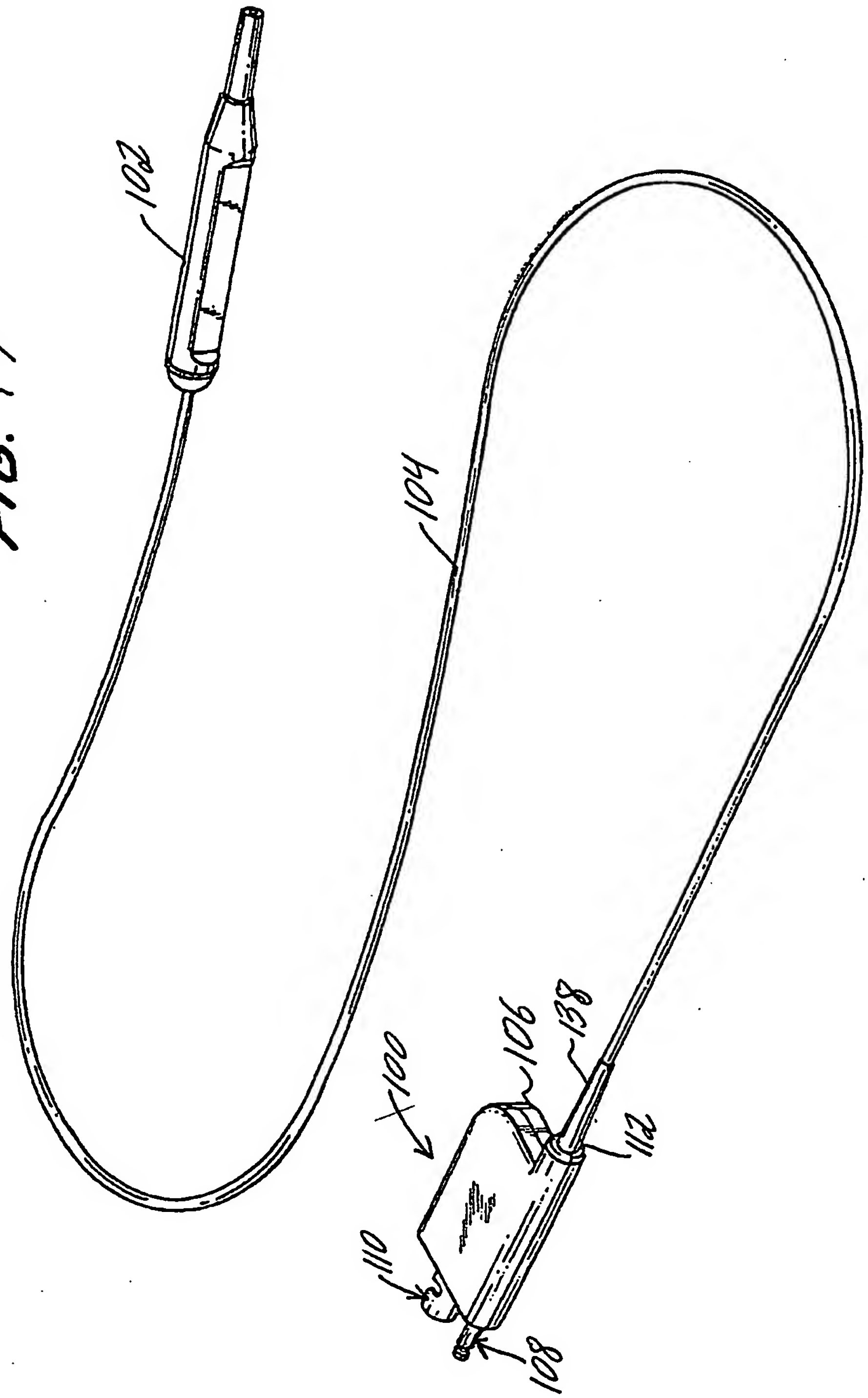
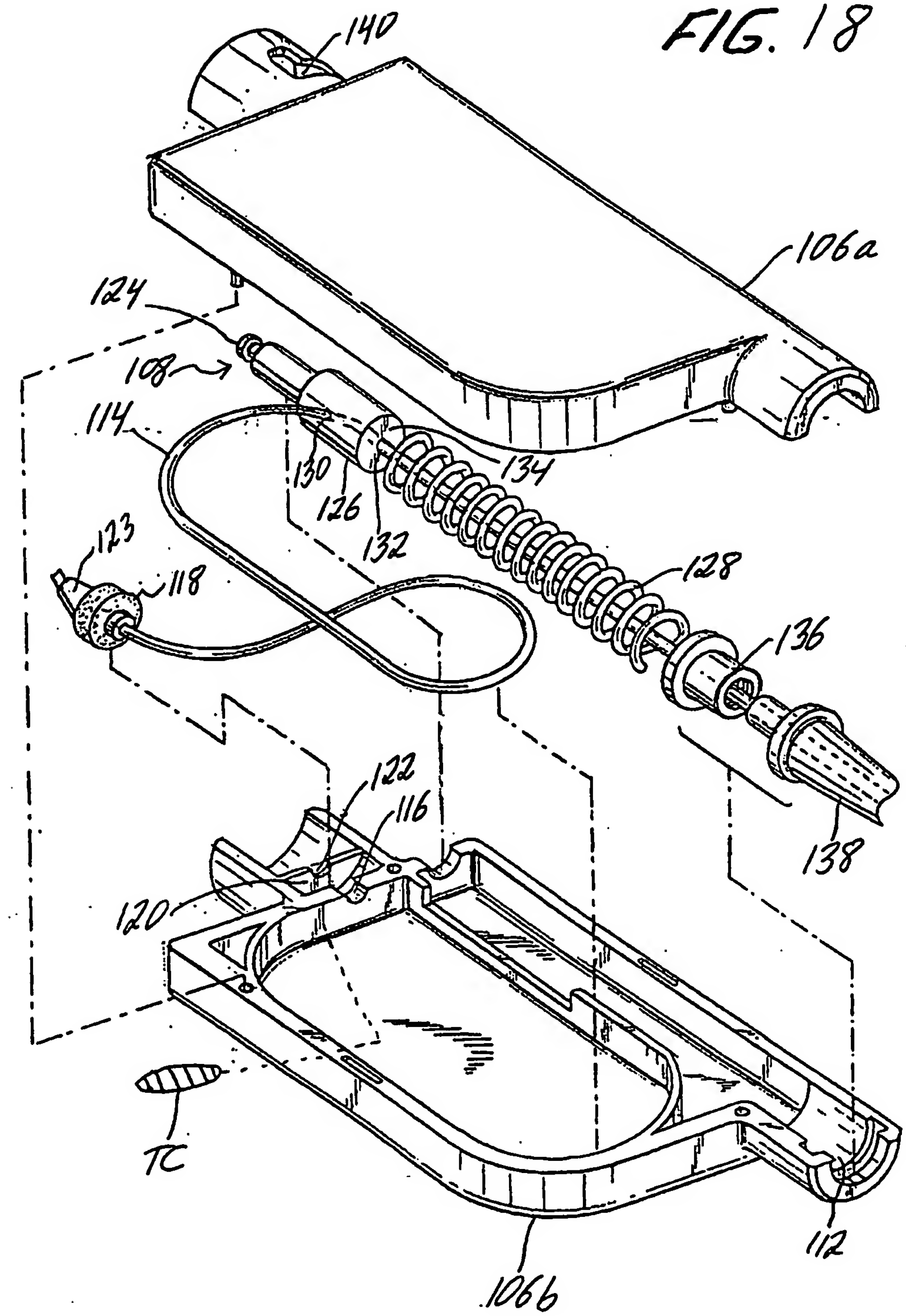


FIG. 18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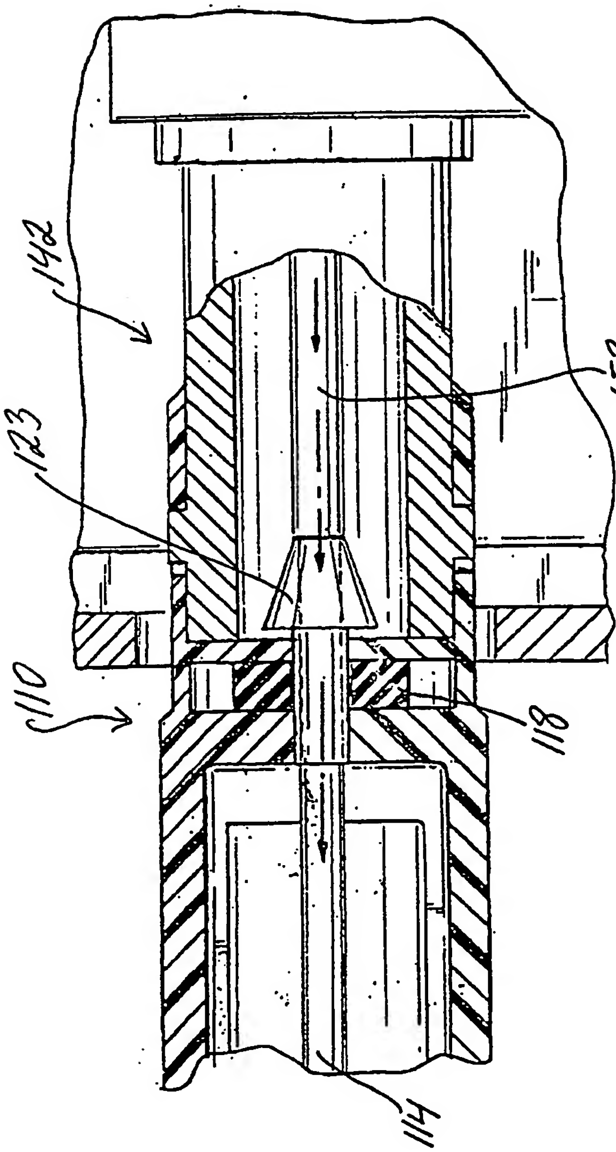
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FIG. 19

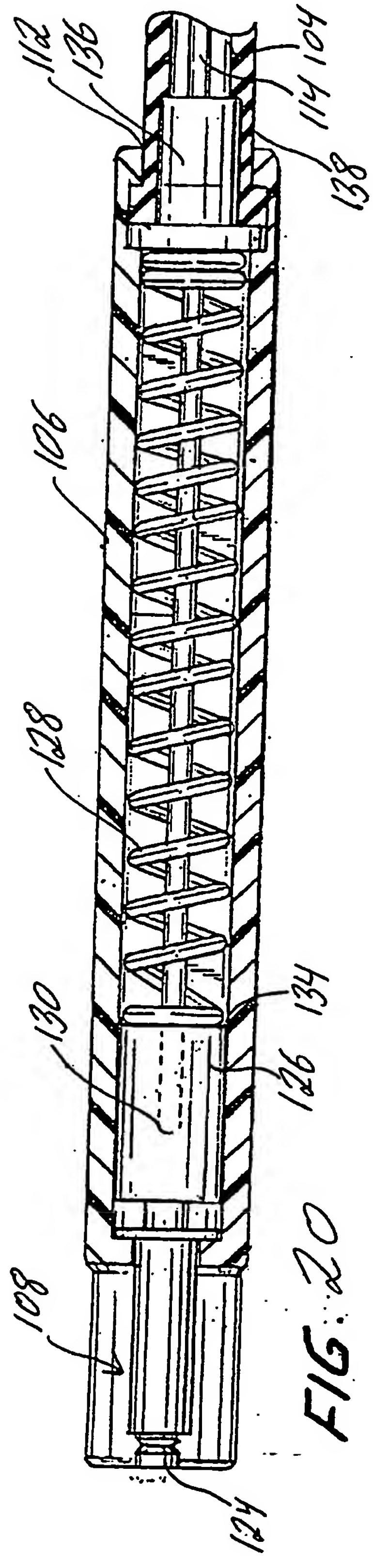
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FIG. 20

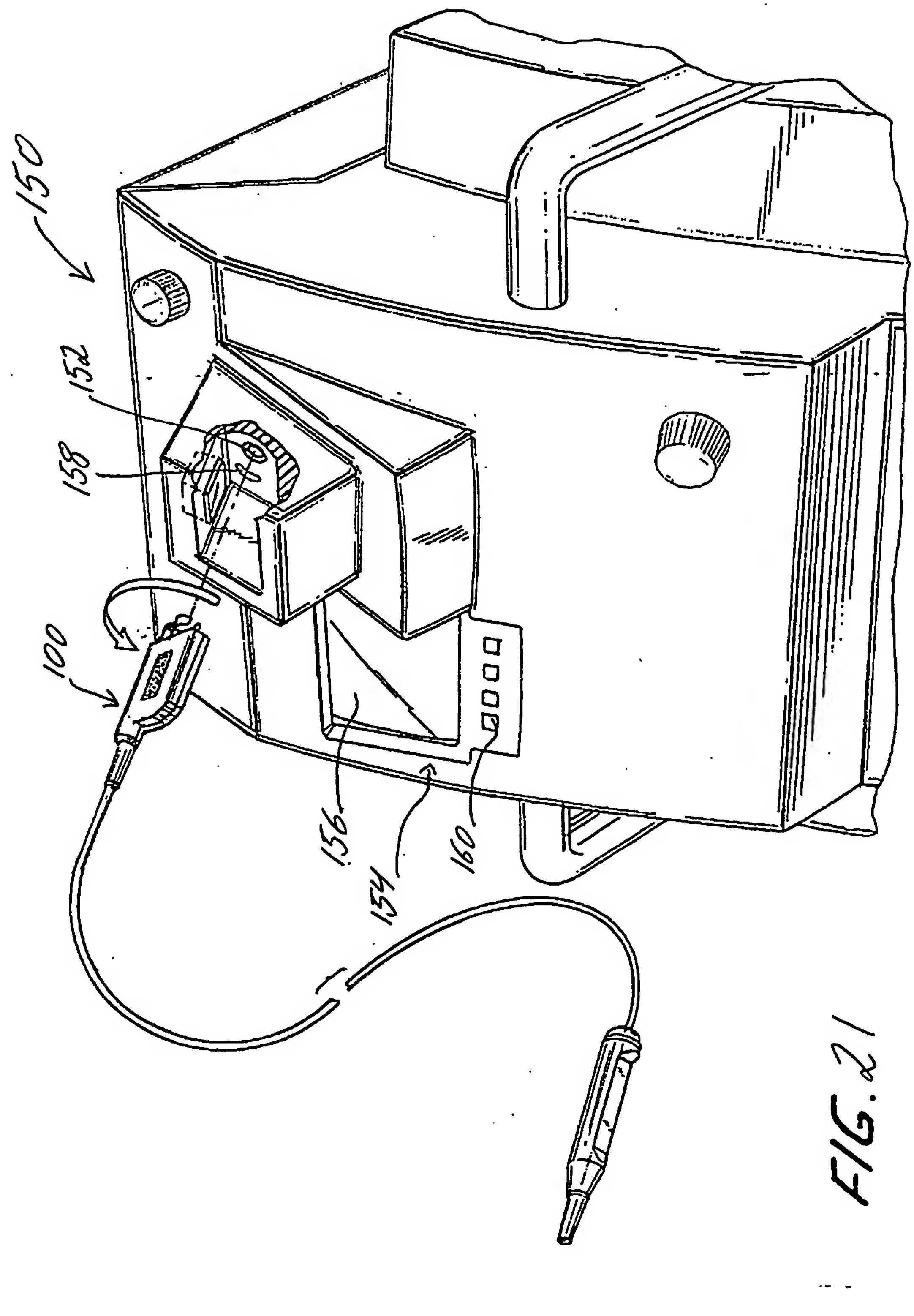


FIG. 21

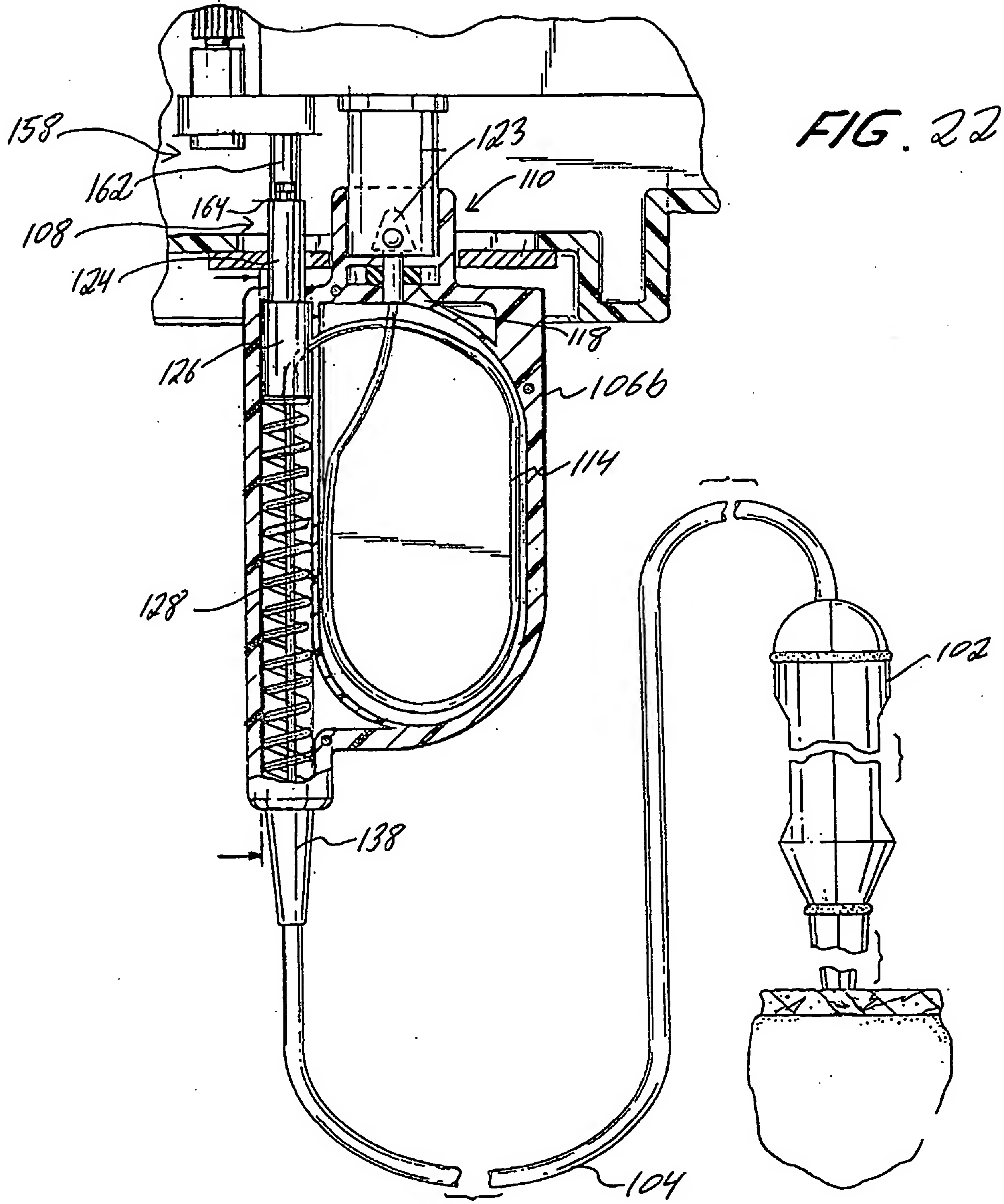


FIG. 22

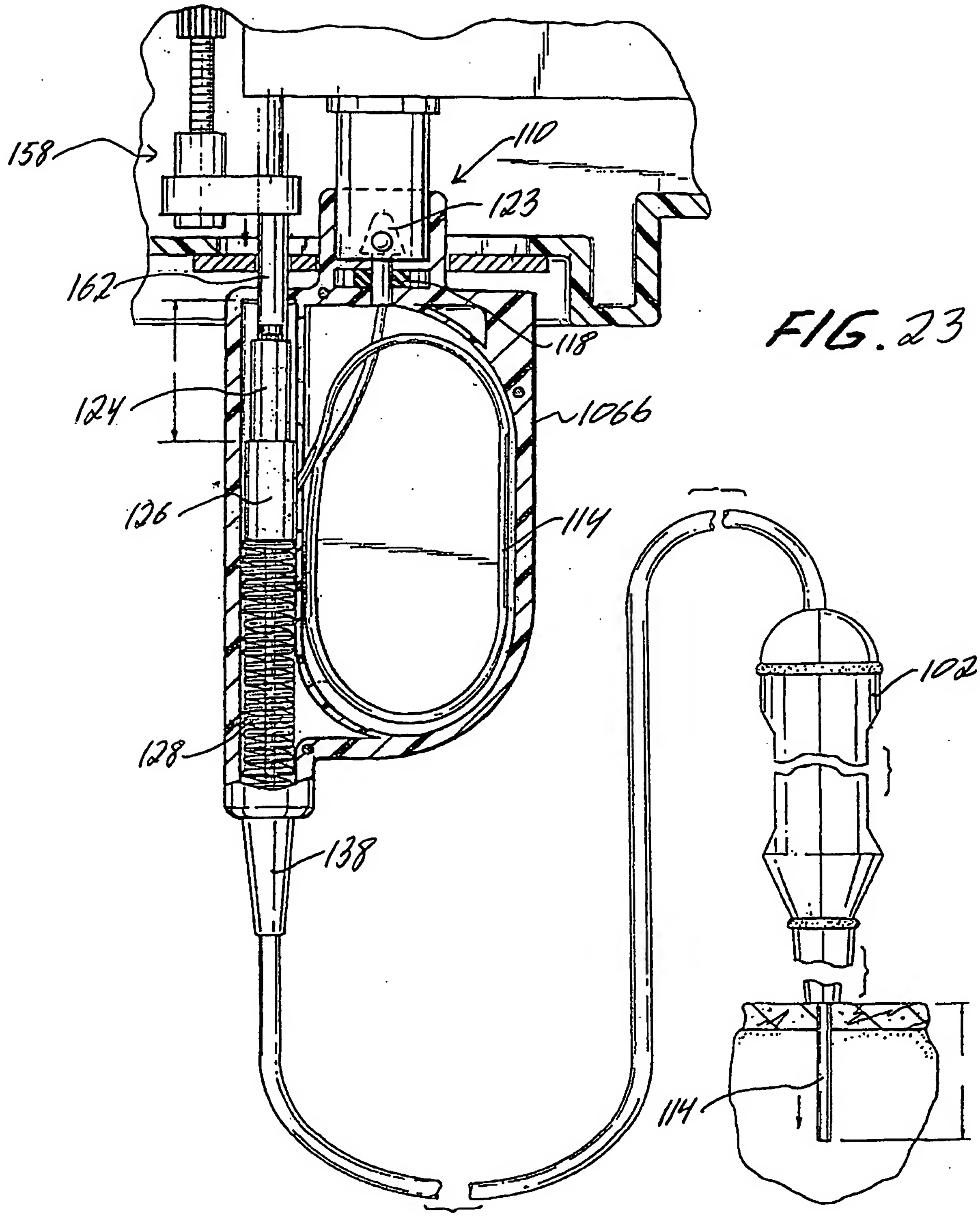


FIG. 23

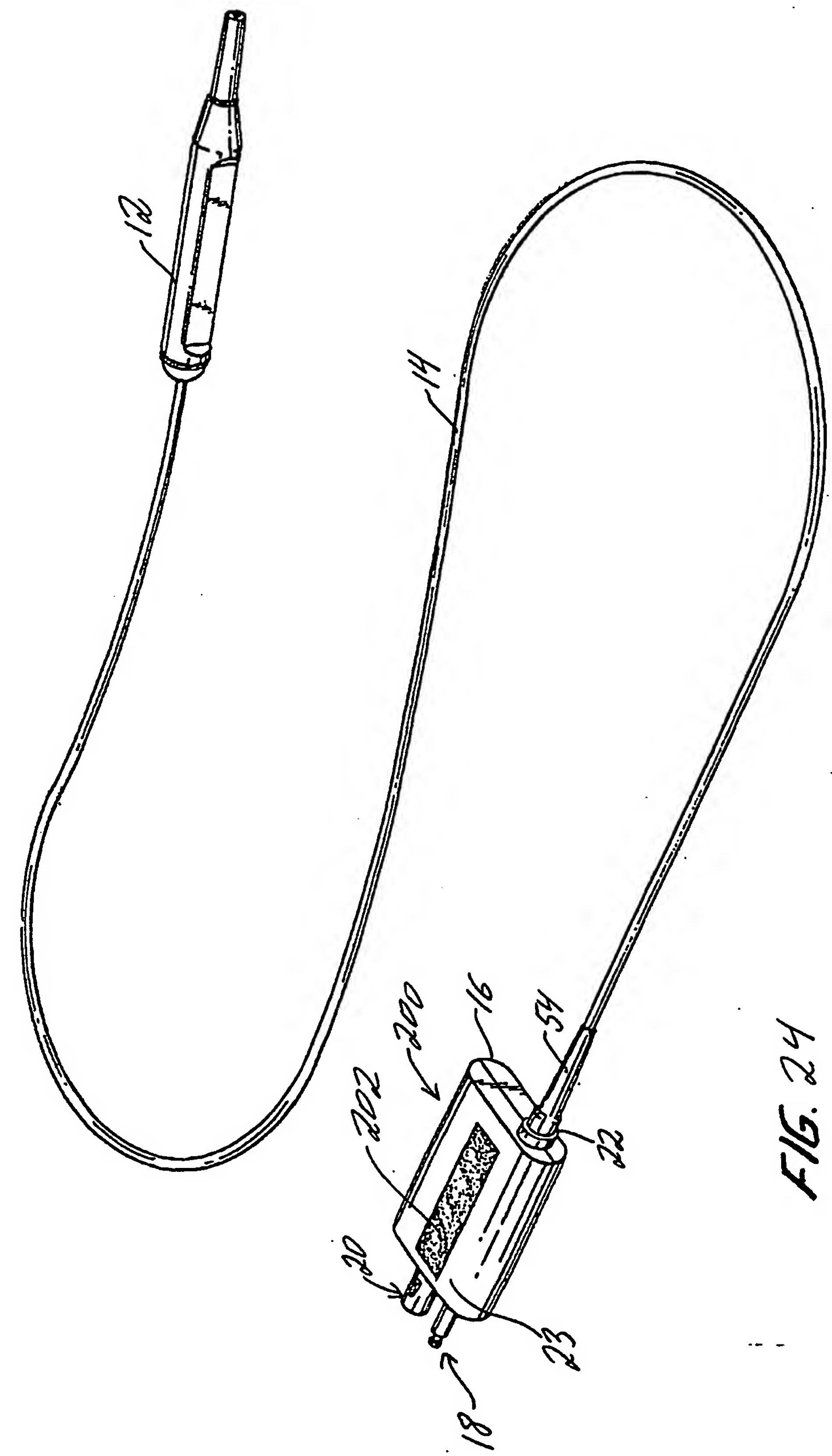
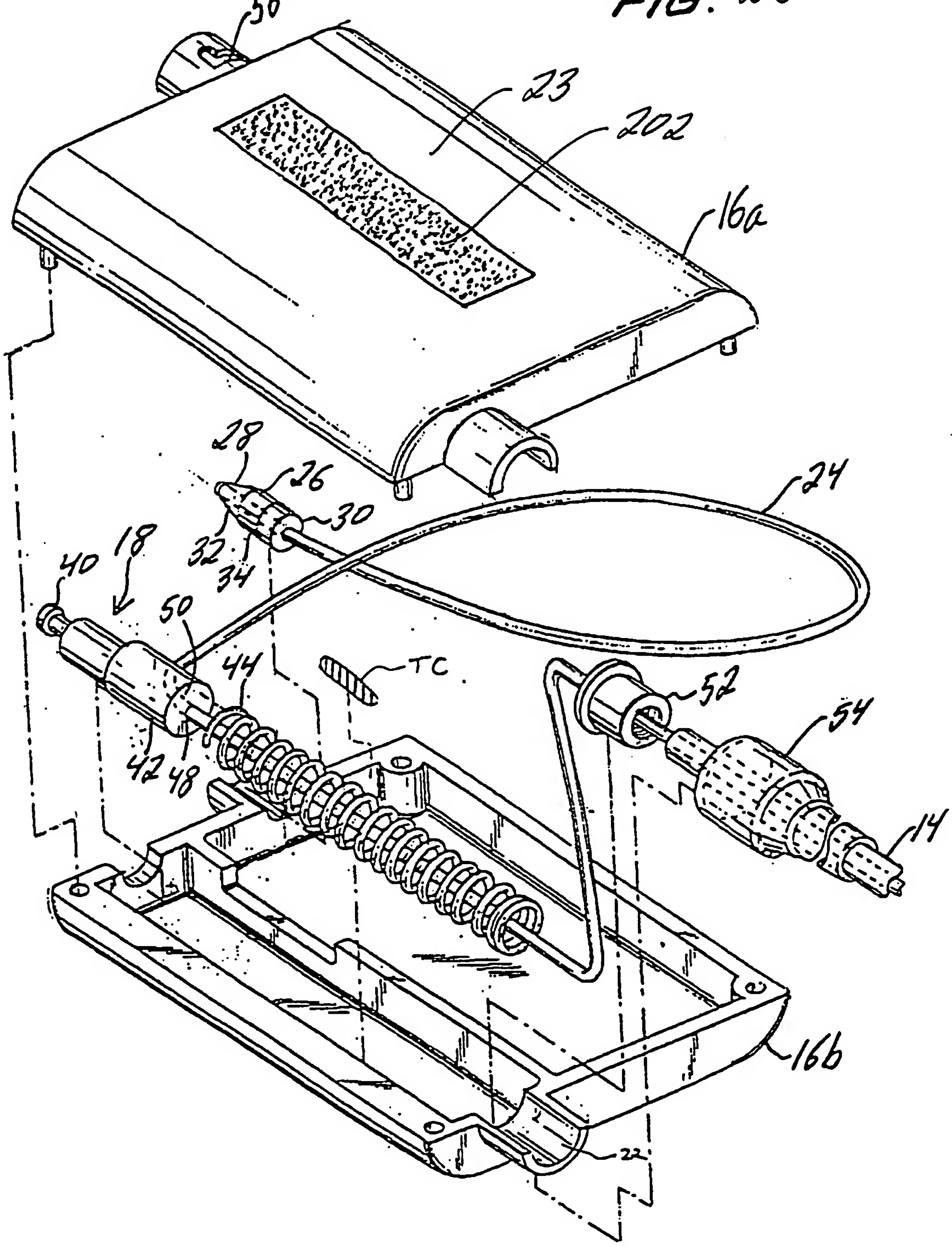


FIG. 24

FIG. 25



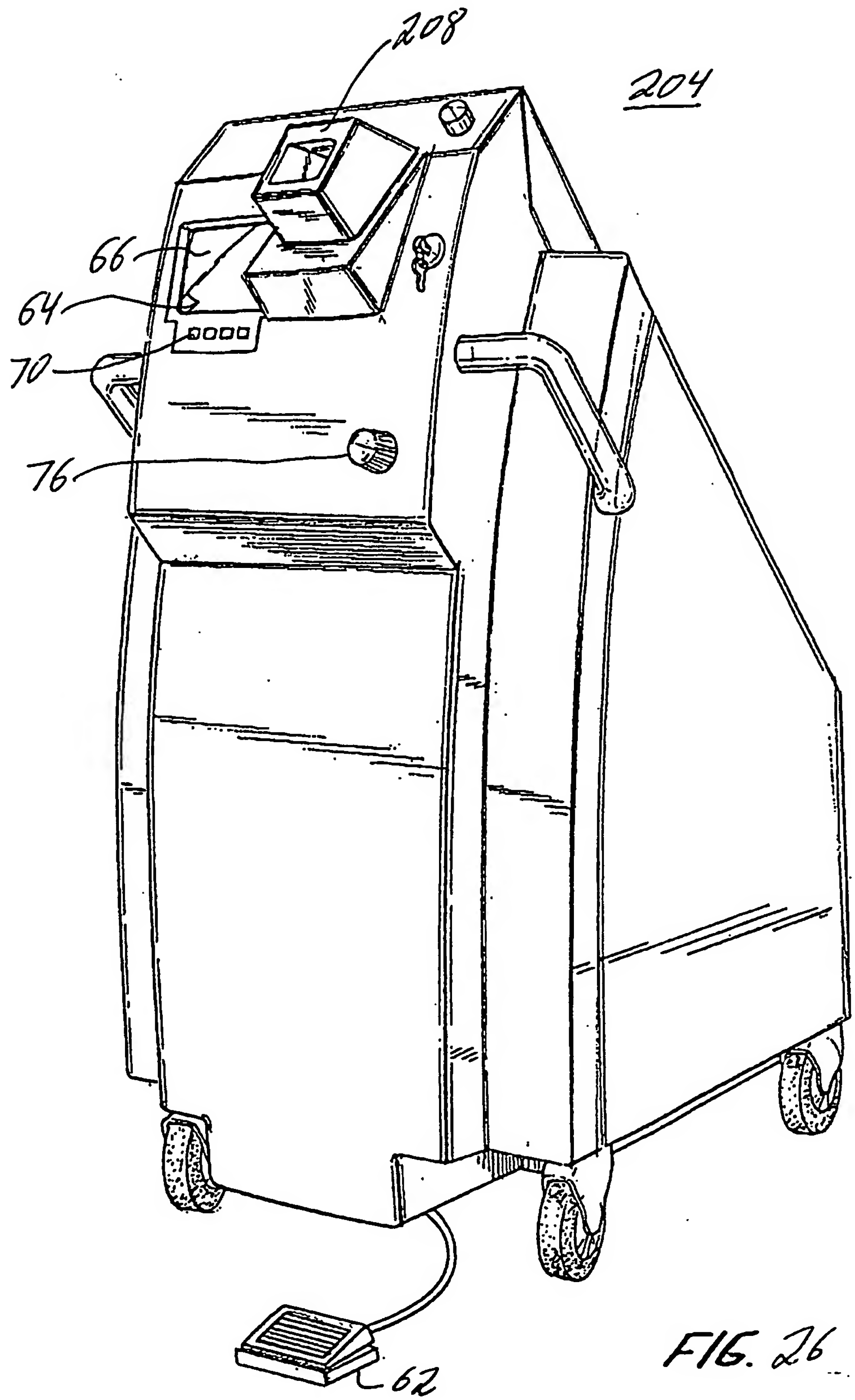


FIG. 26

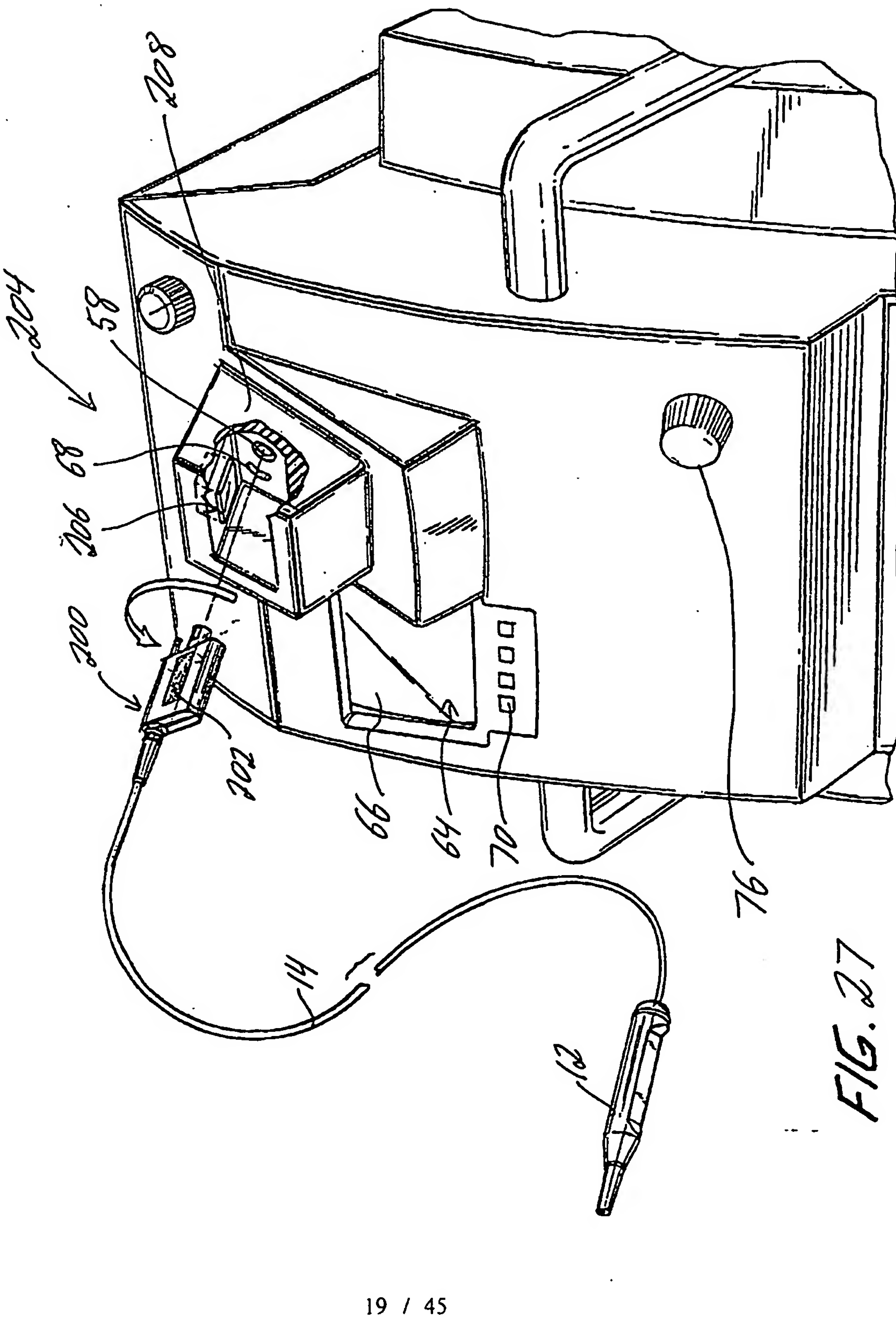


FIG. 27

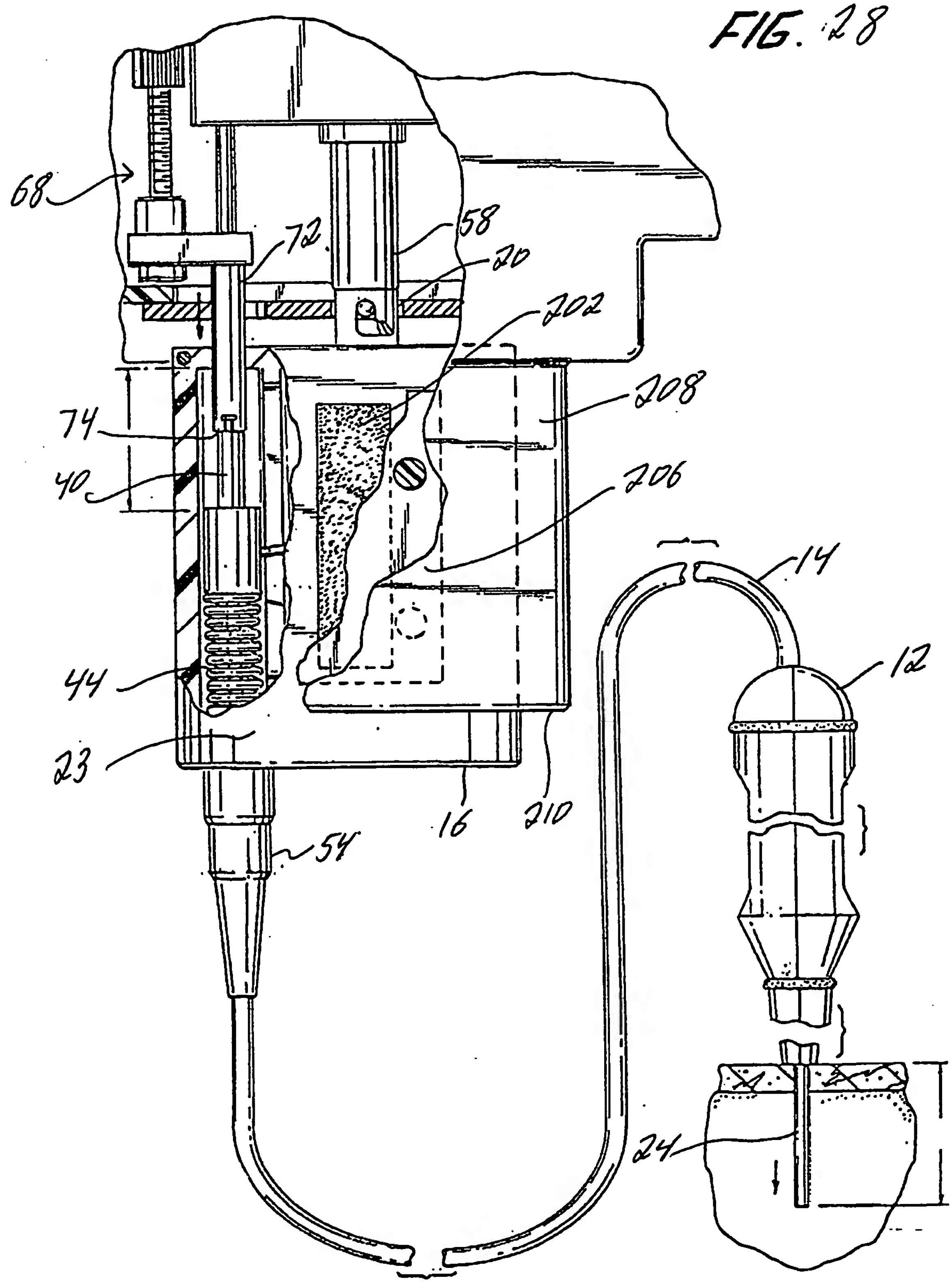


FIG. 28
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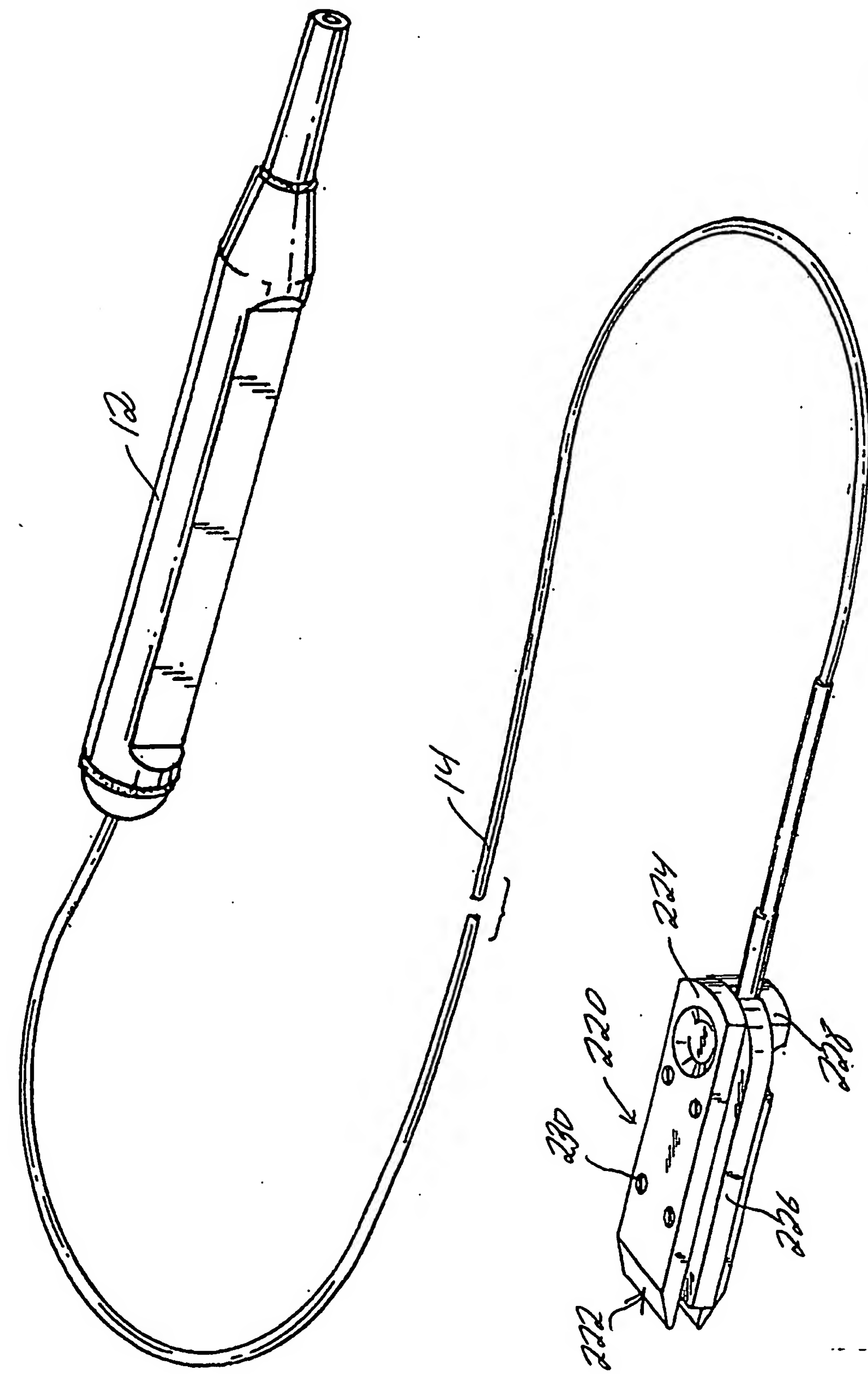


FIG. 29

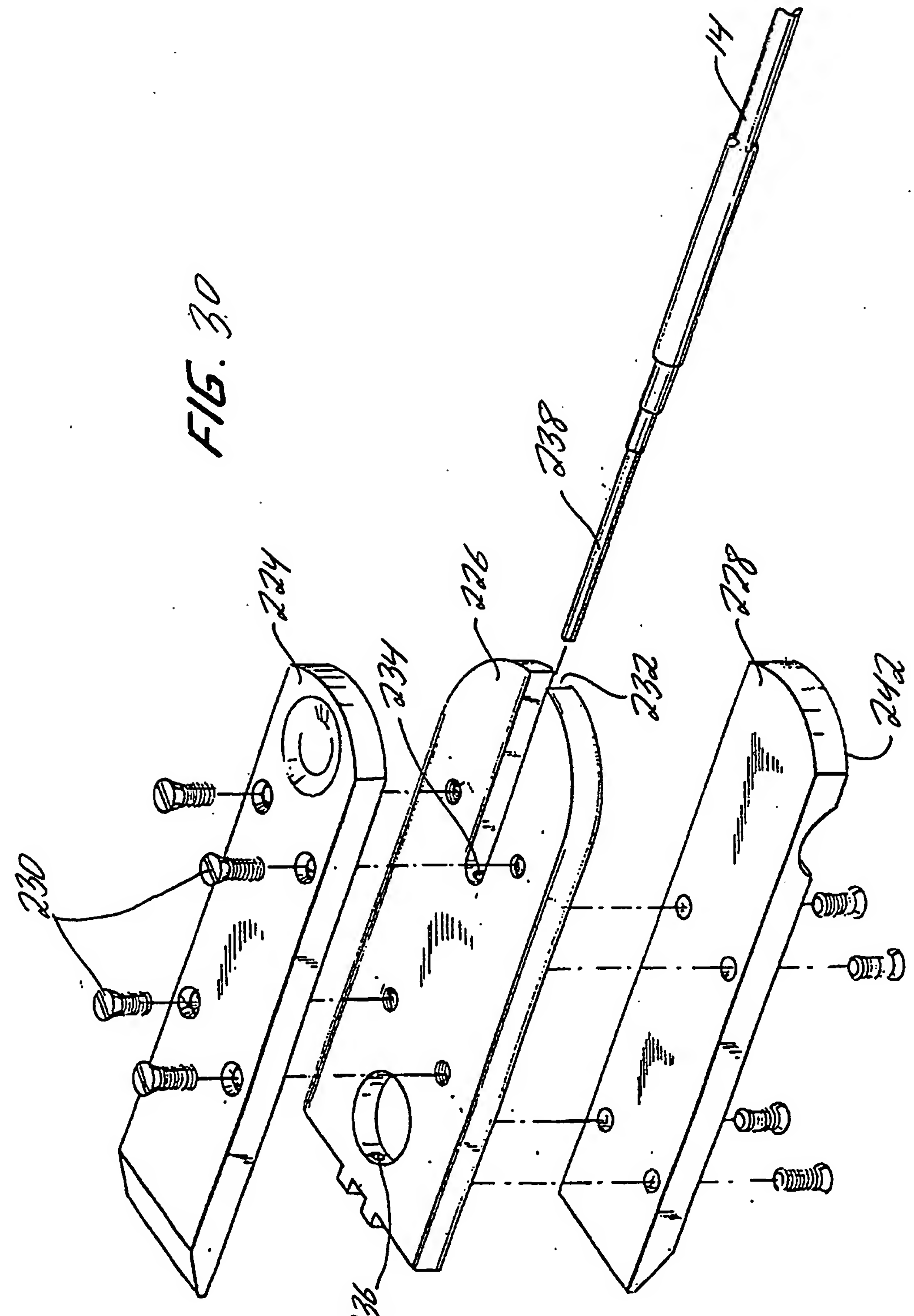


FIG. 30

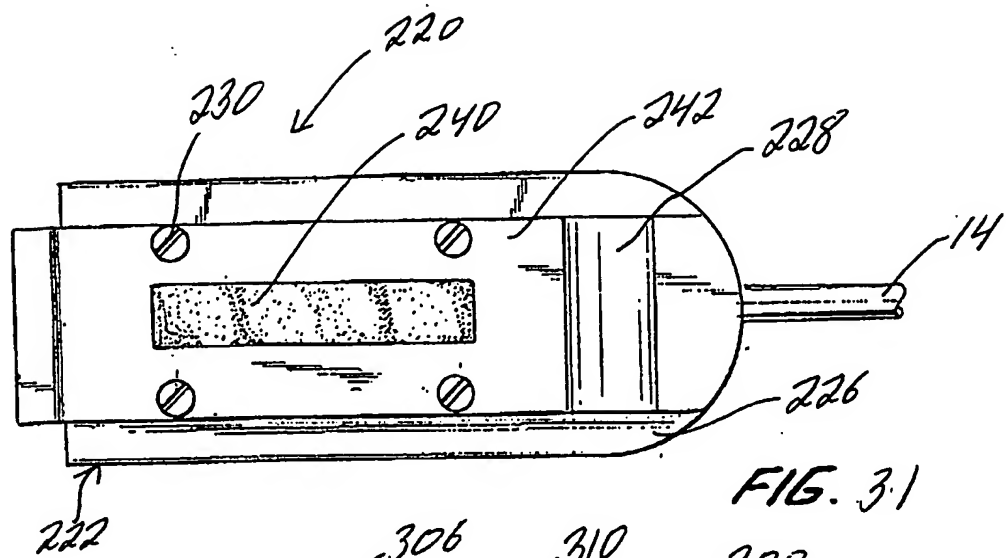


FIG. 31

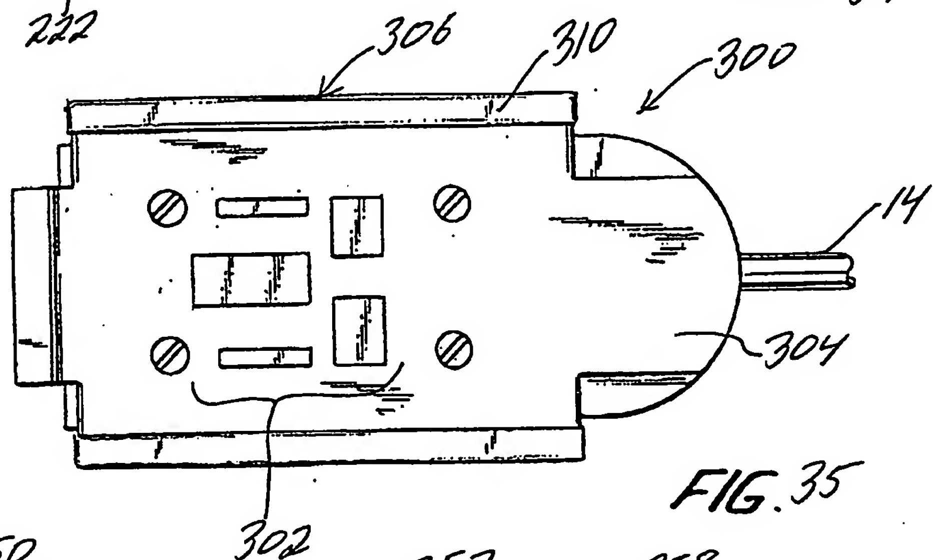


FIG. 35

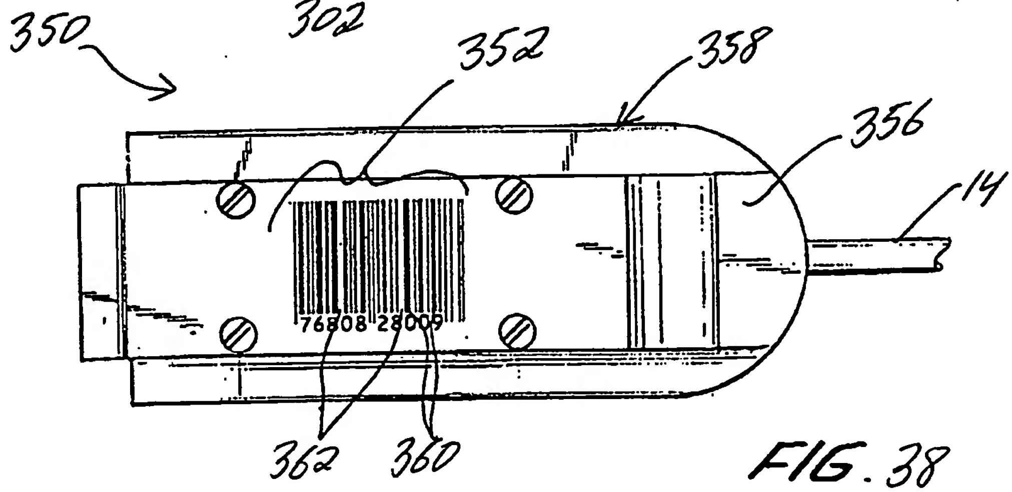
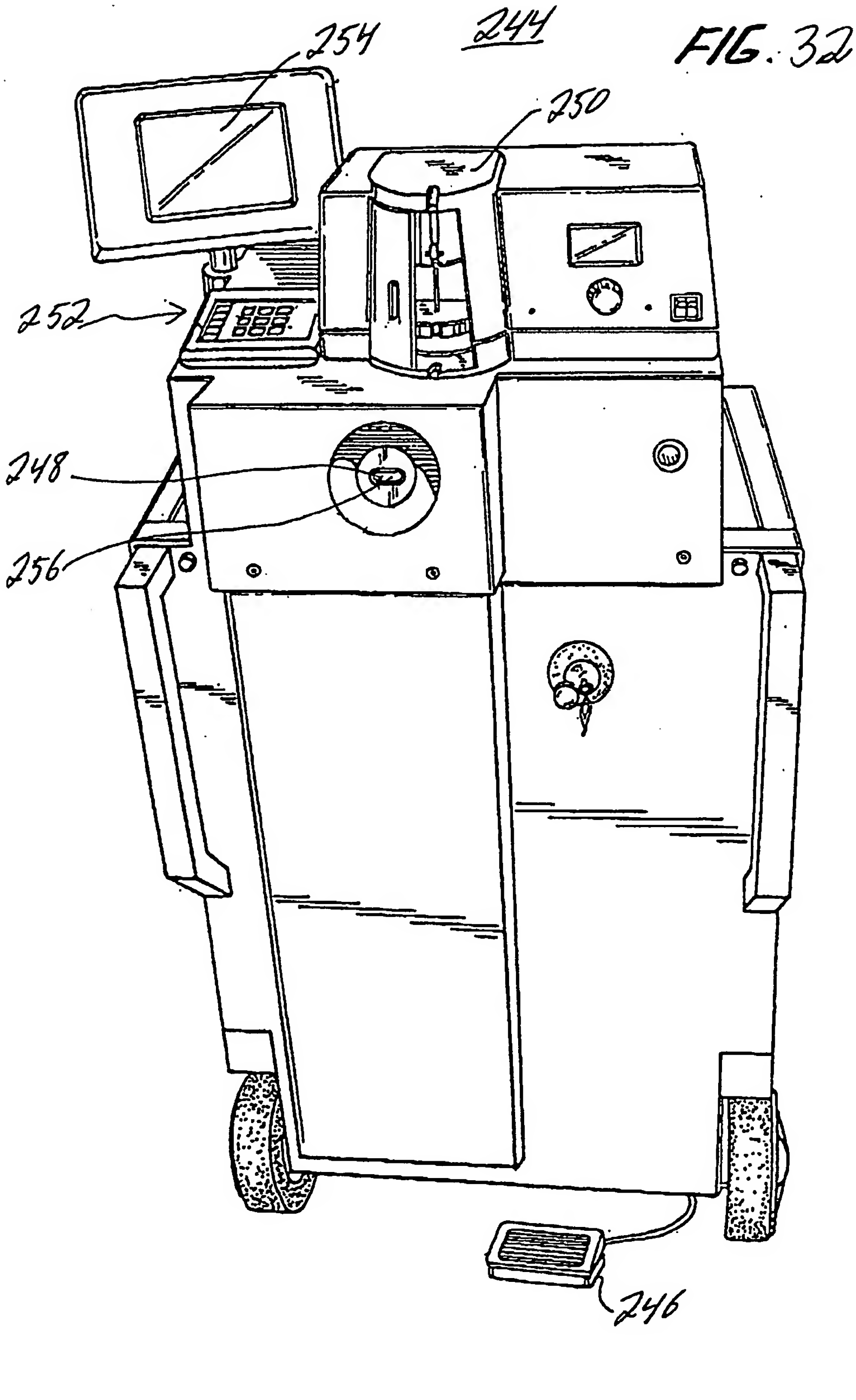


FIG. 38

FIG. 32



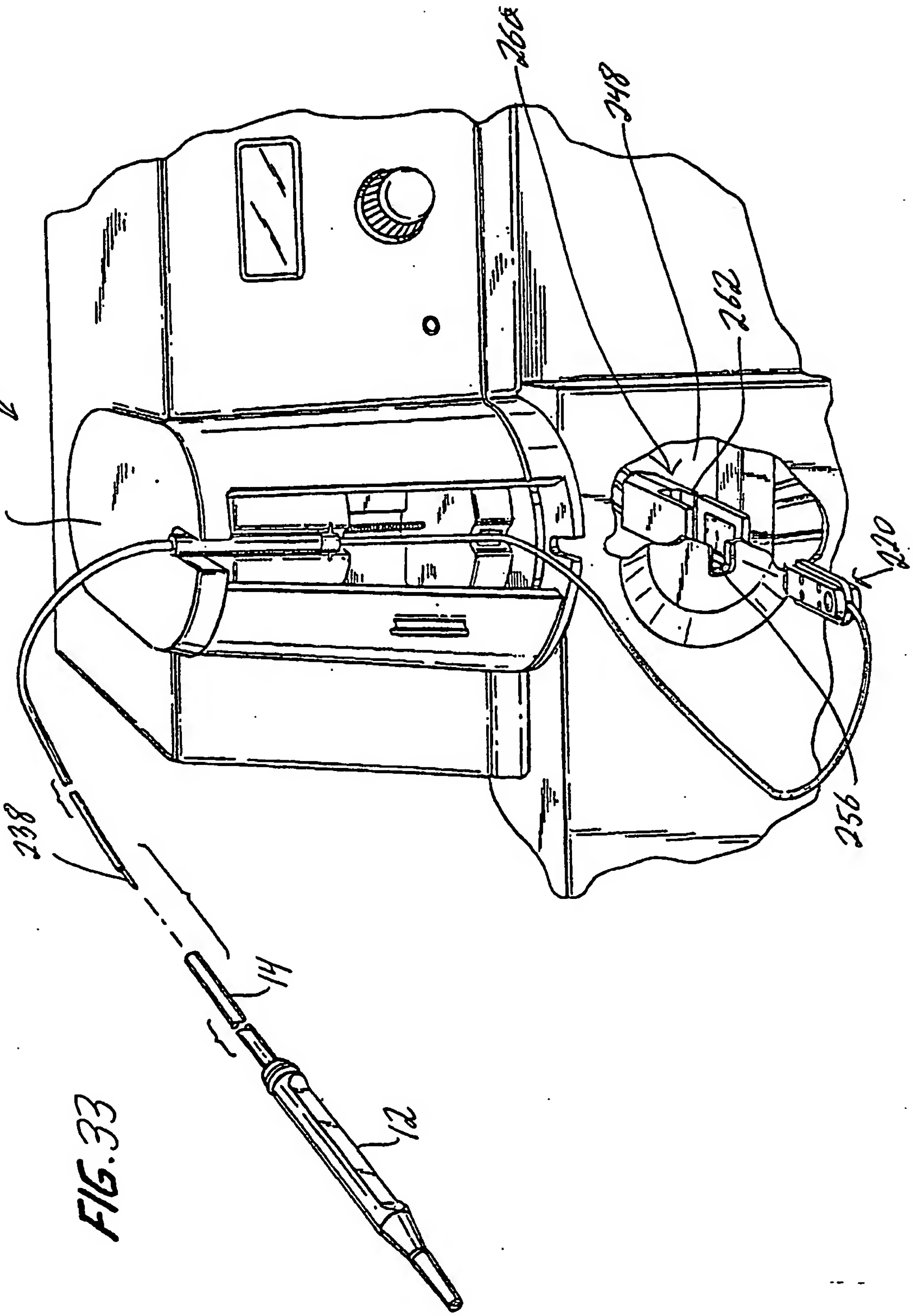


FIG. 33

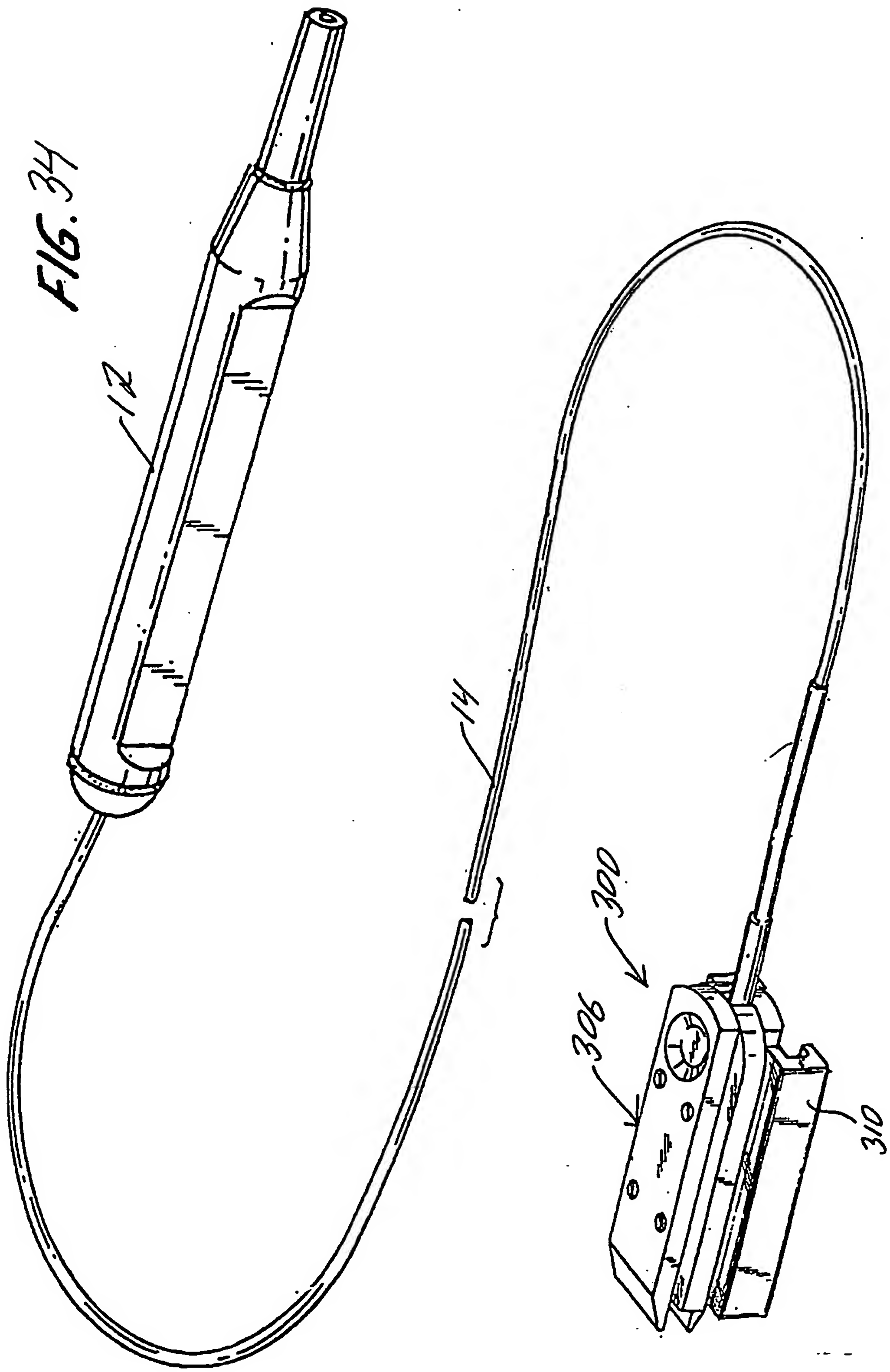


FIG. 34

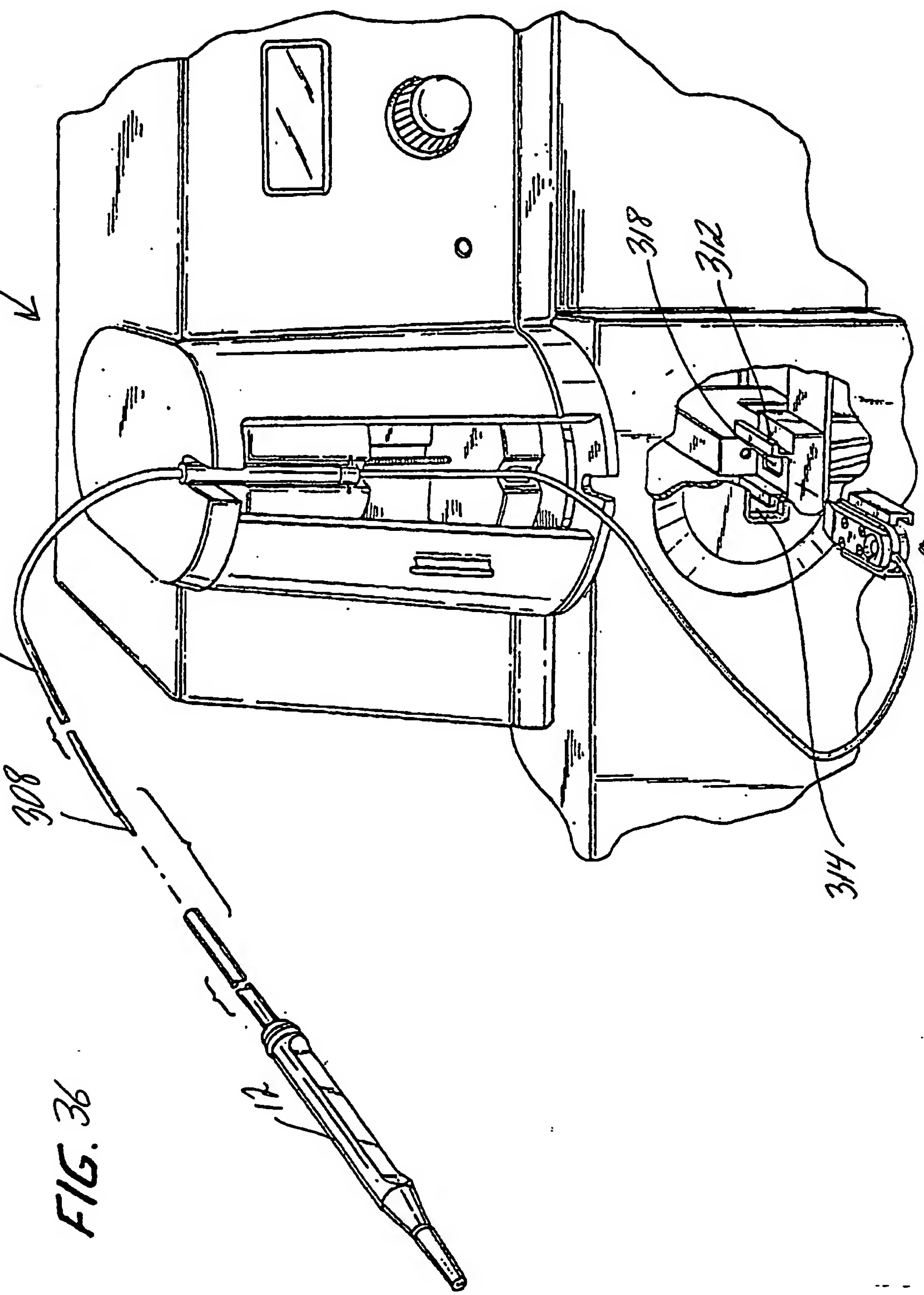


FIG. 36

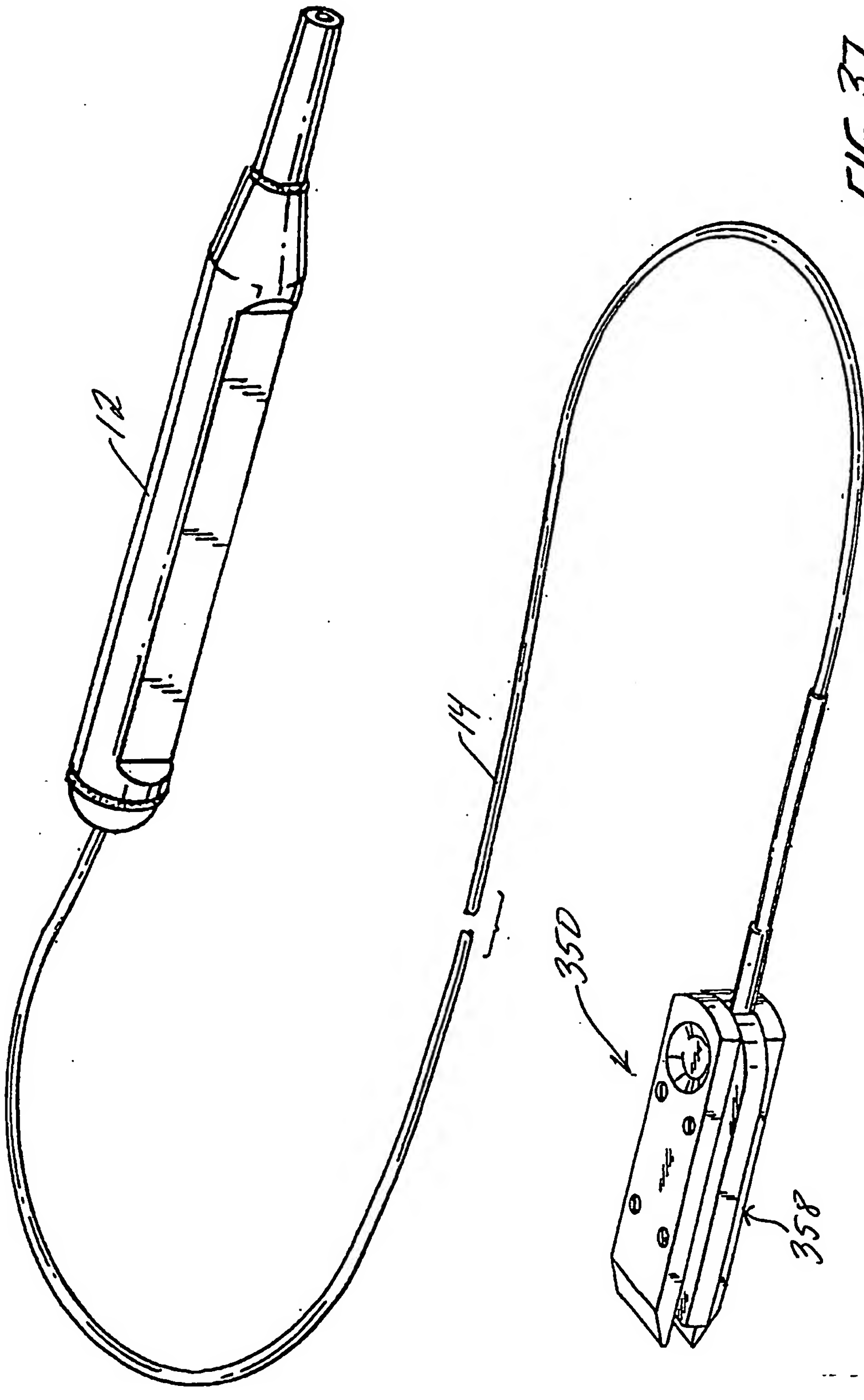


FIG. 37

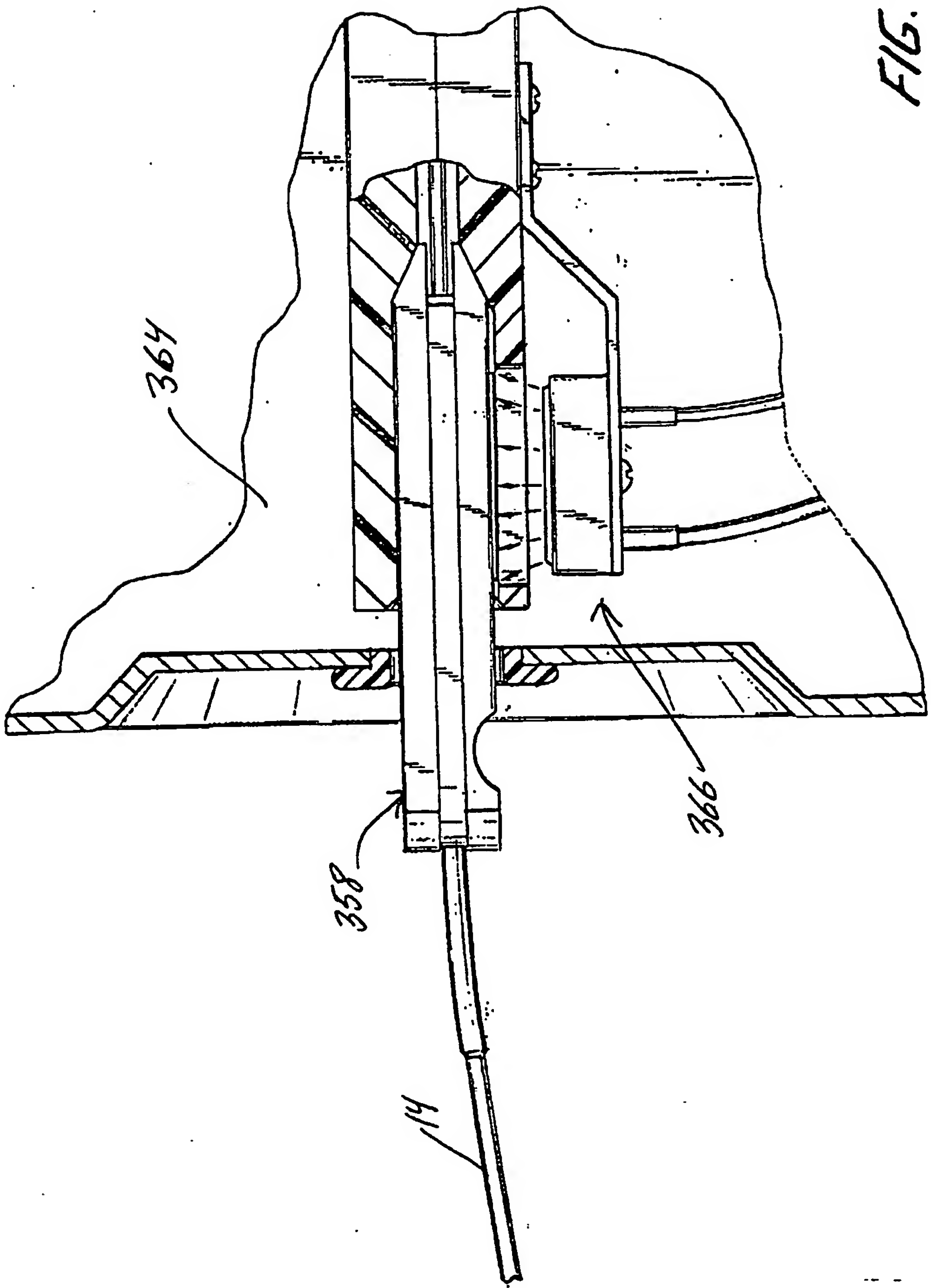


FIG. 39

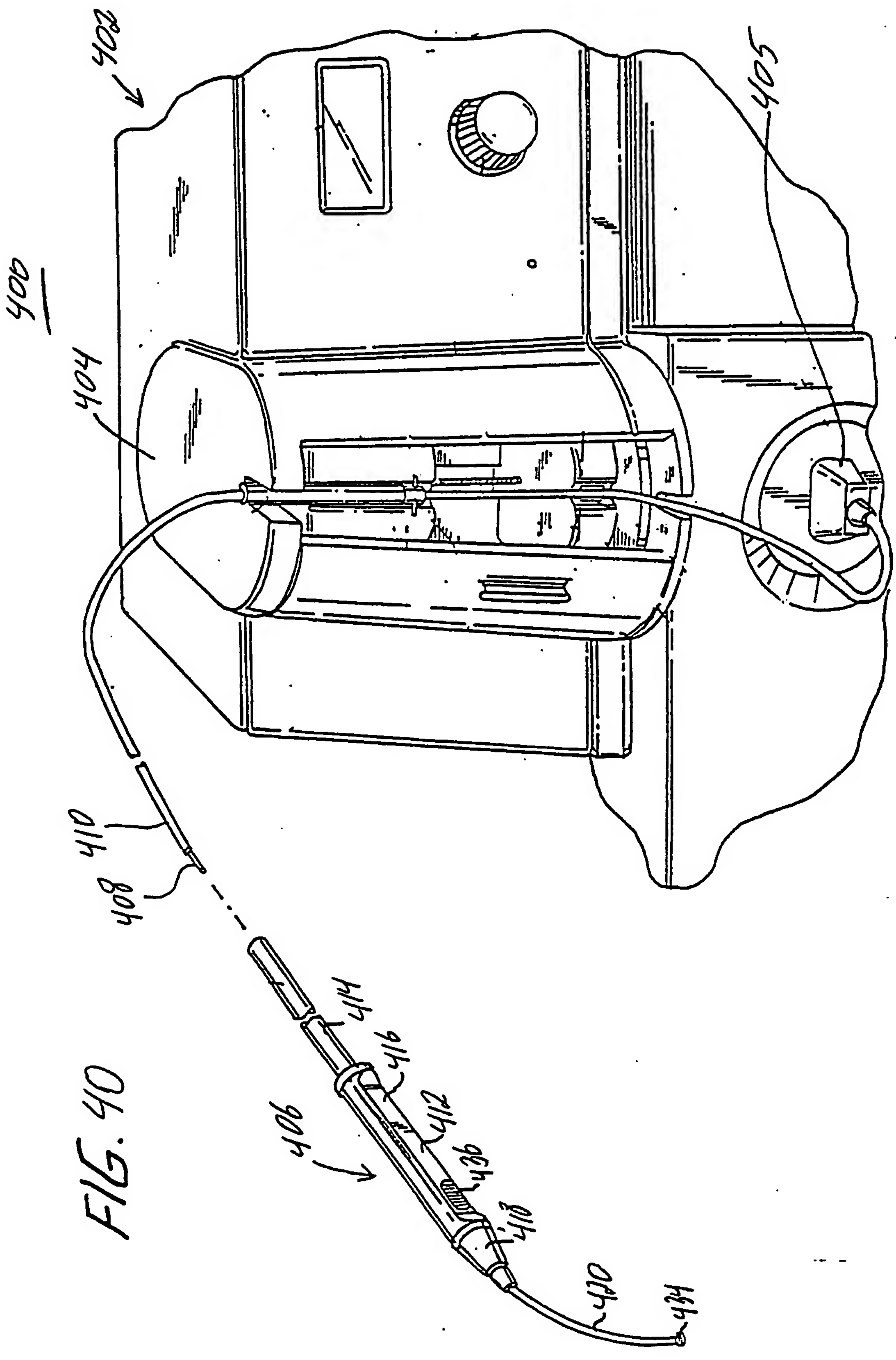


FIG. 40

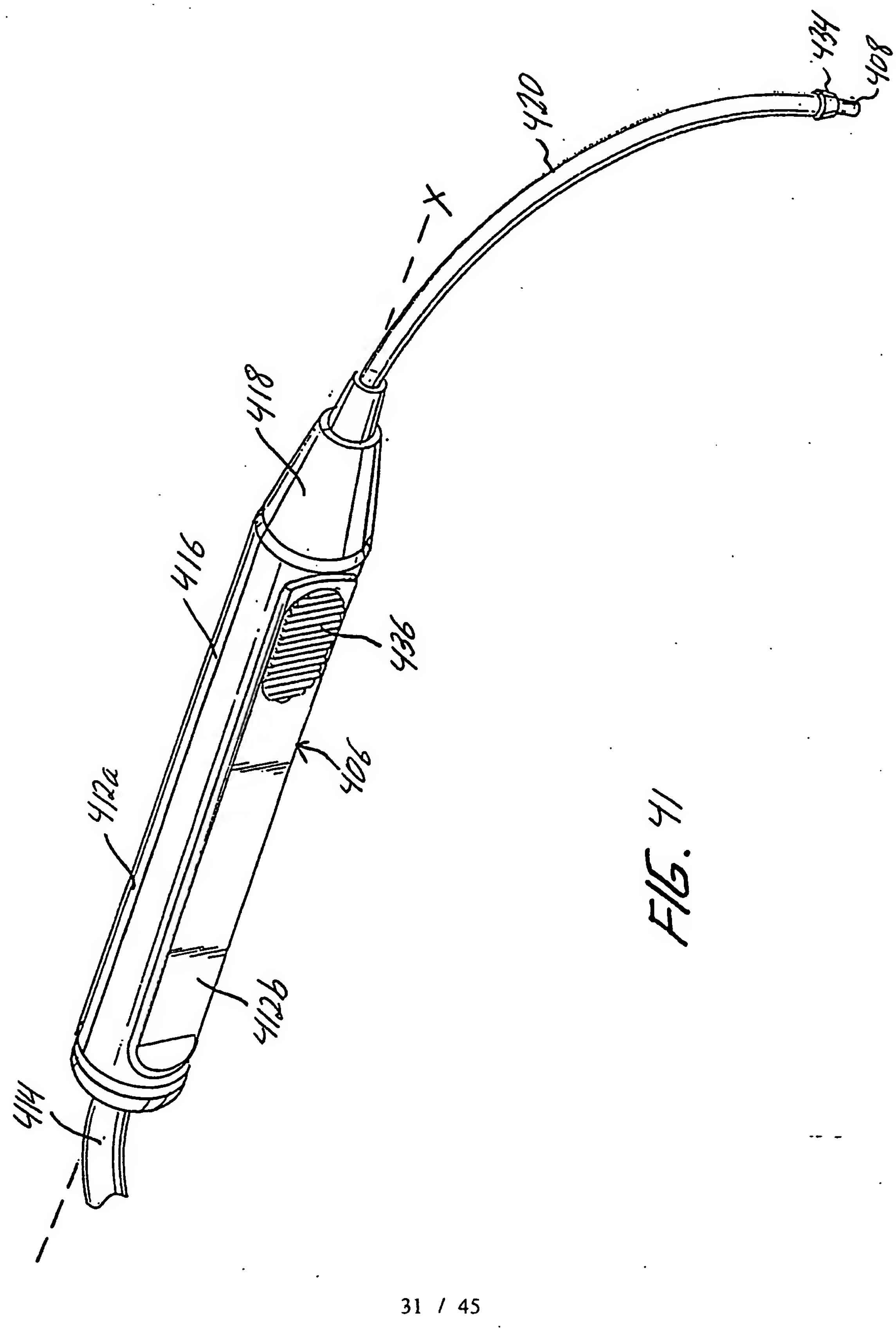


FIG. 41

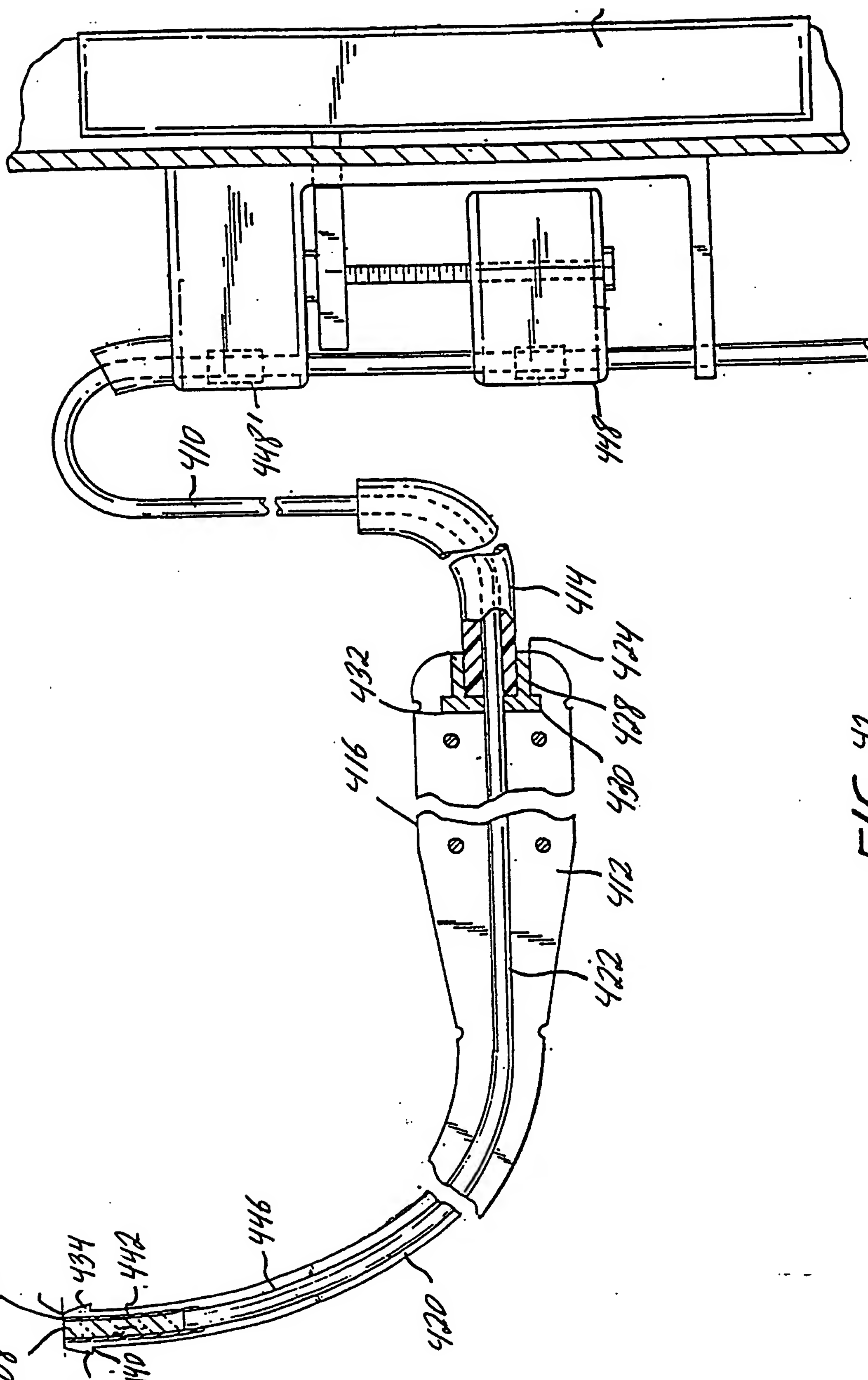

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FIG. 42

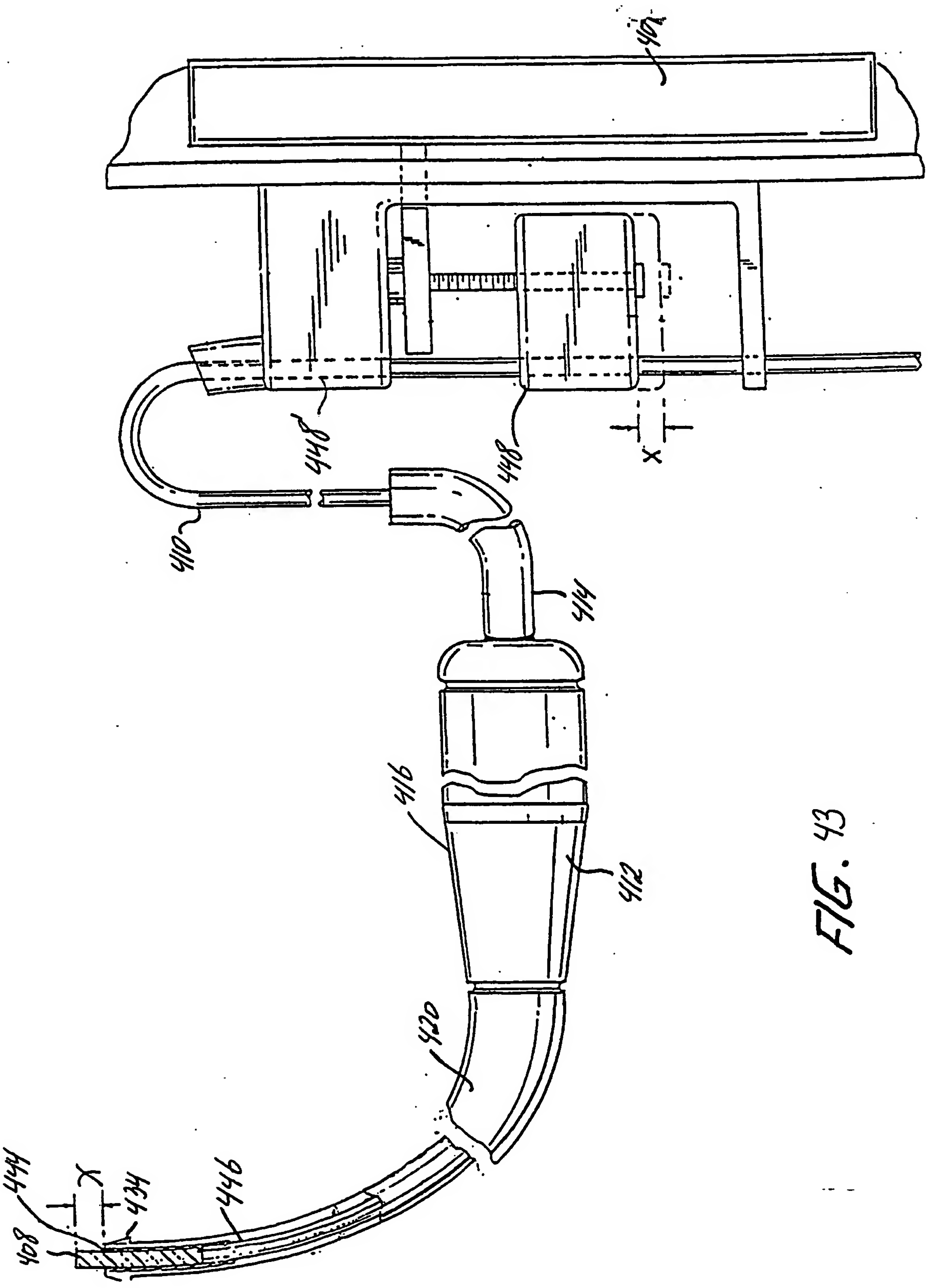


FIG. 43

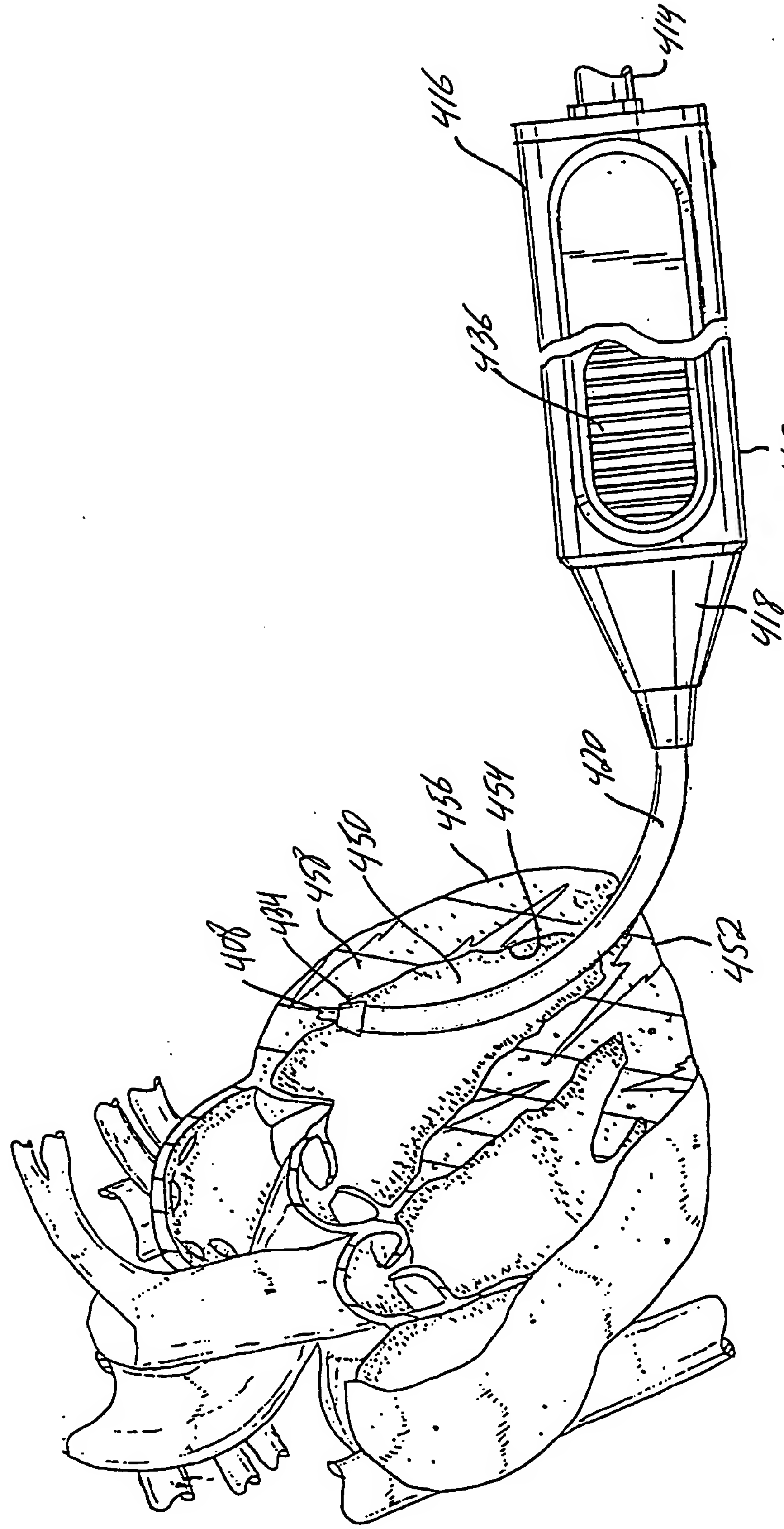
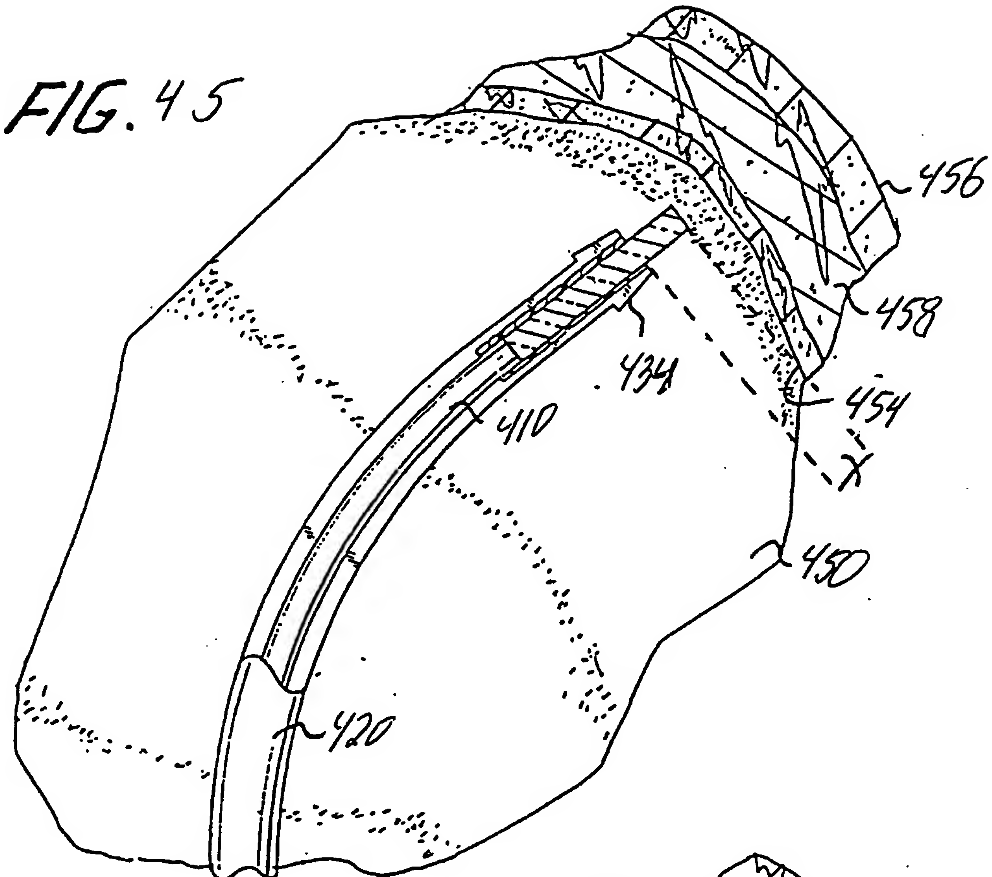


FIG. 44

FIG. 45



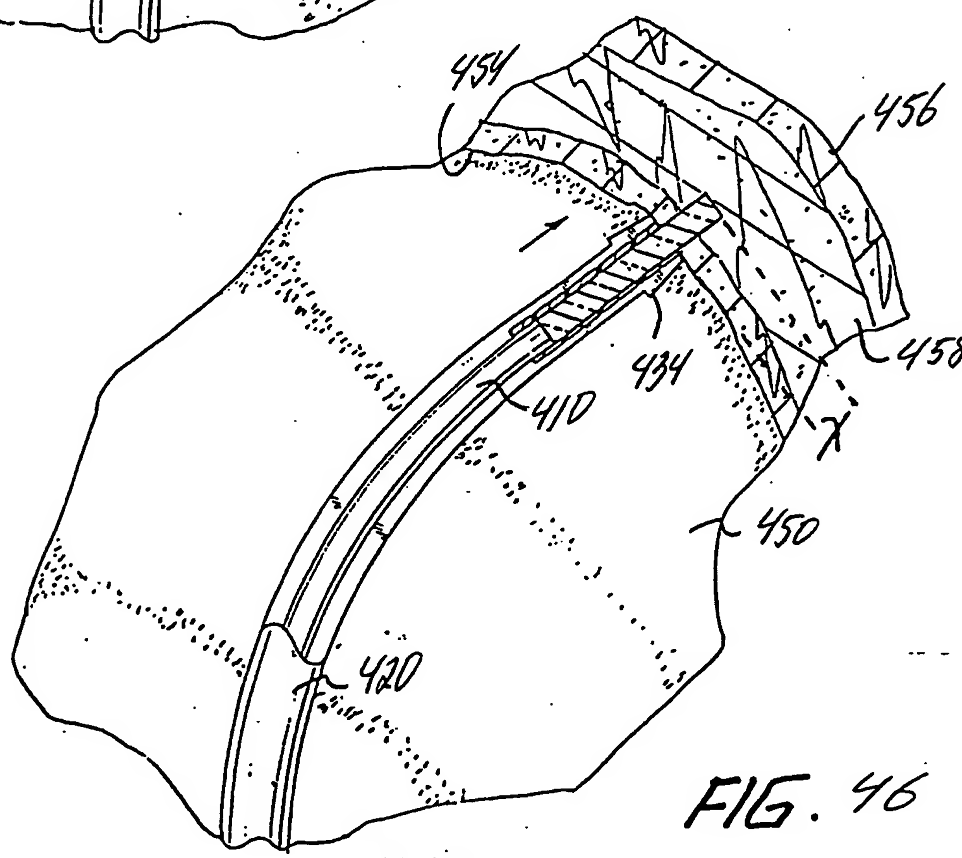
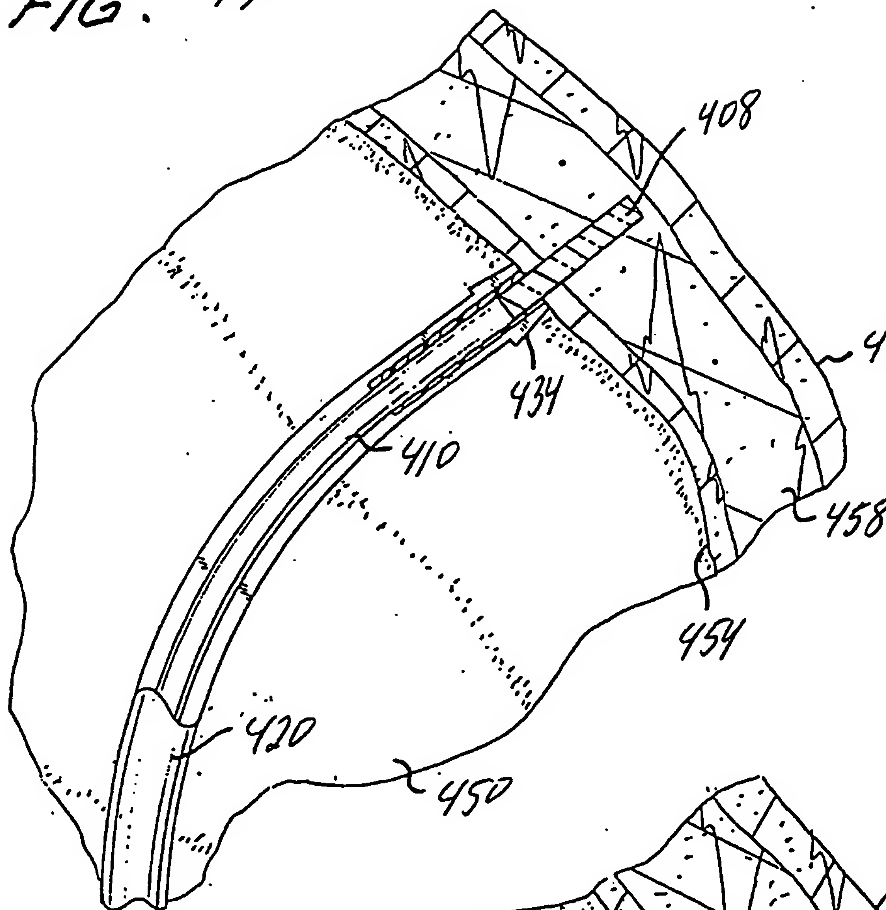


FIG. 46

FIG. 47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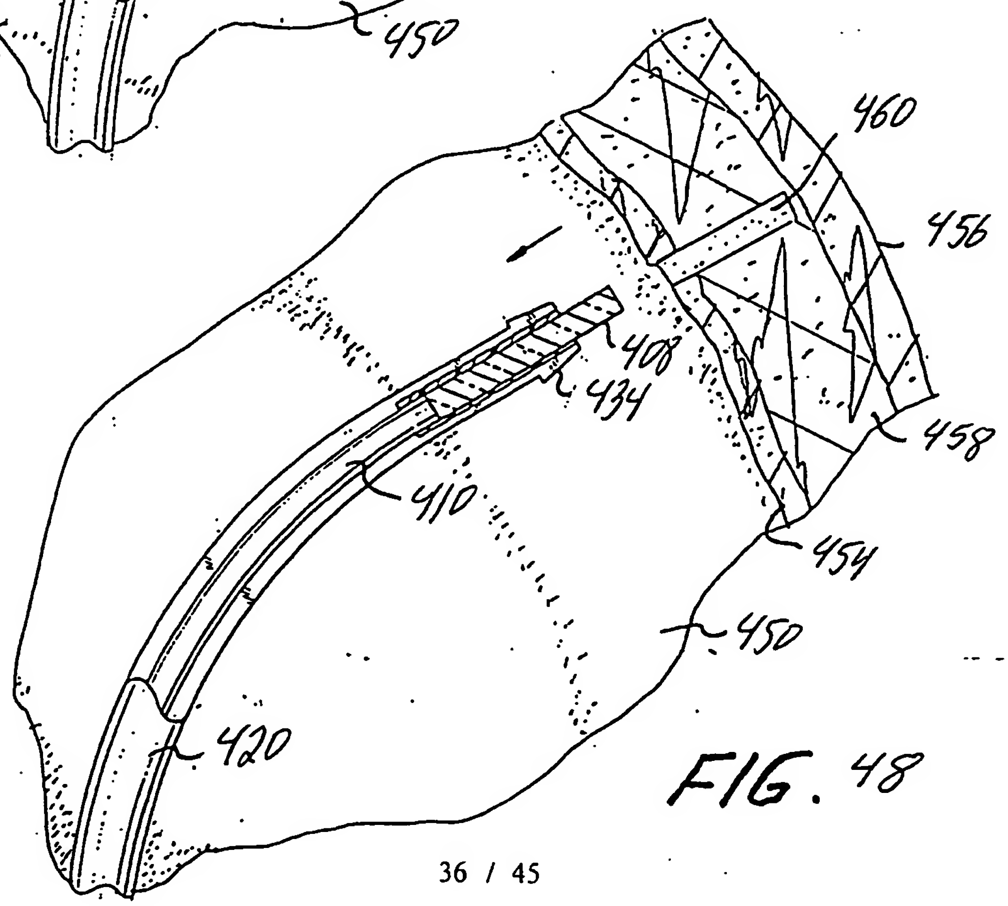
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FIG. 48

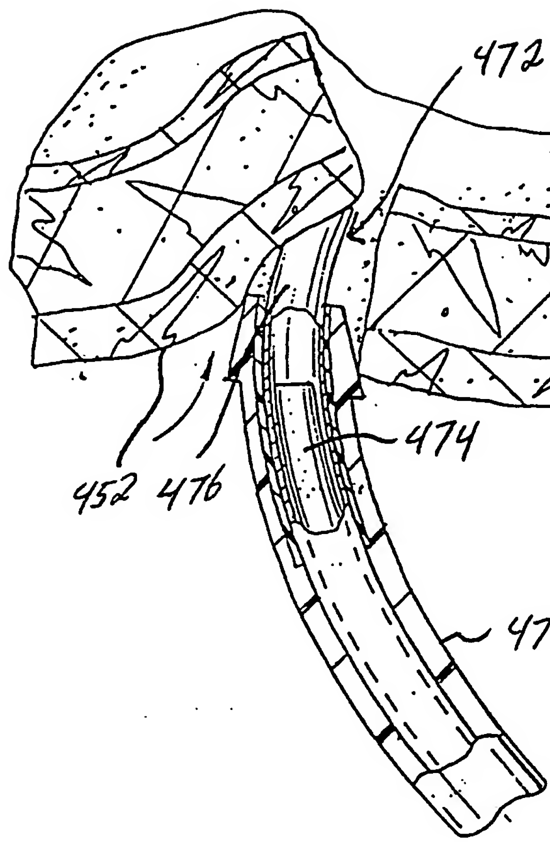
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FIG. 49

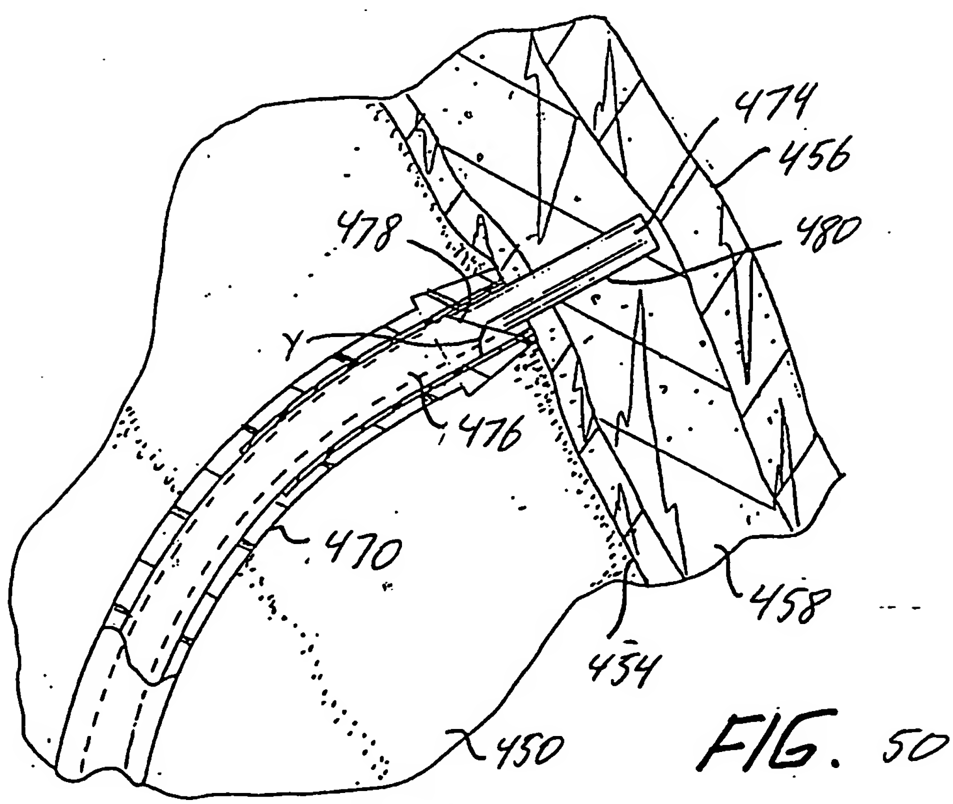
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FIG. 50

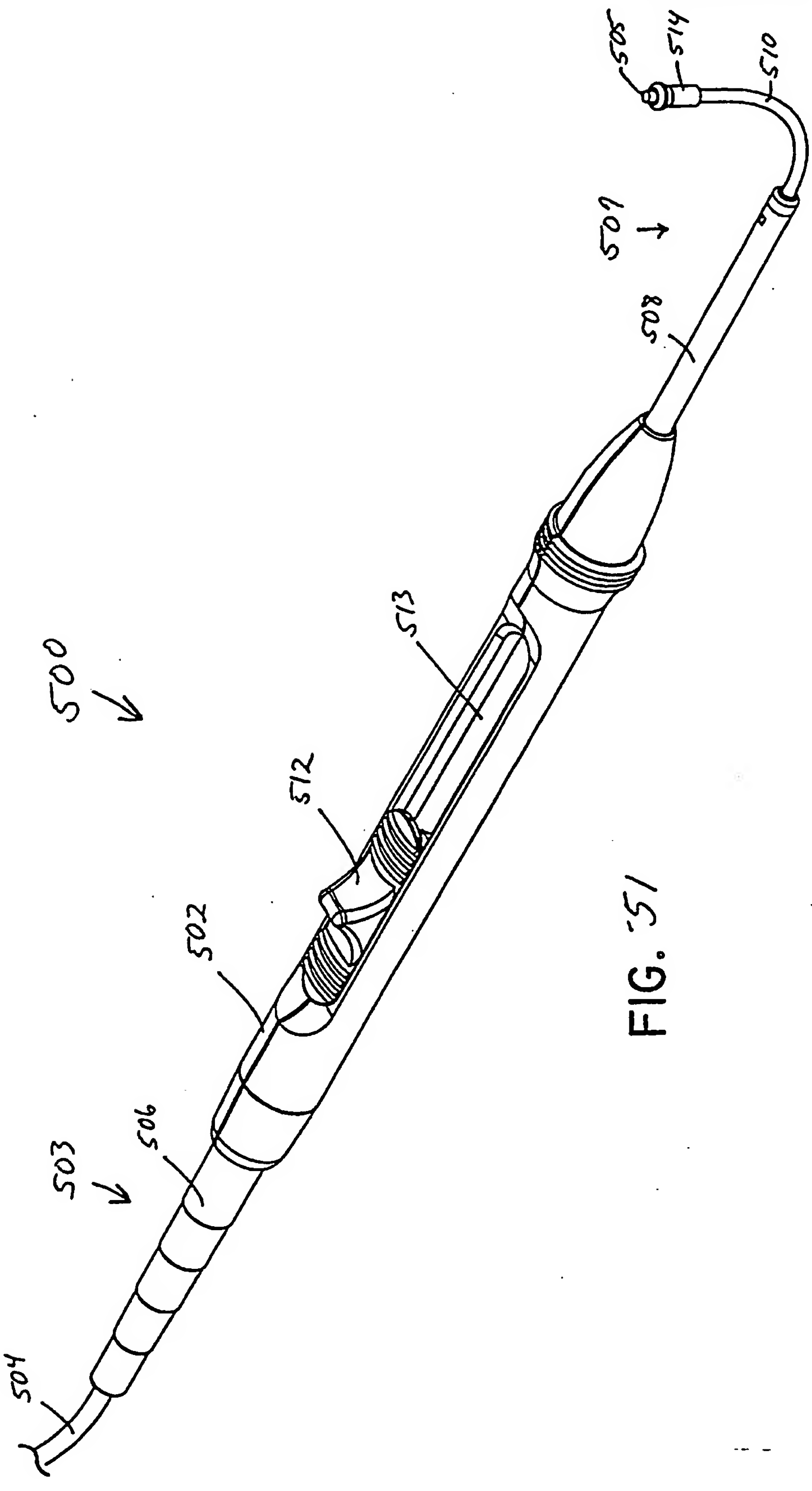

FIG. 51

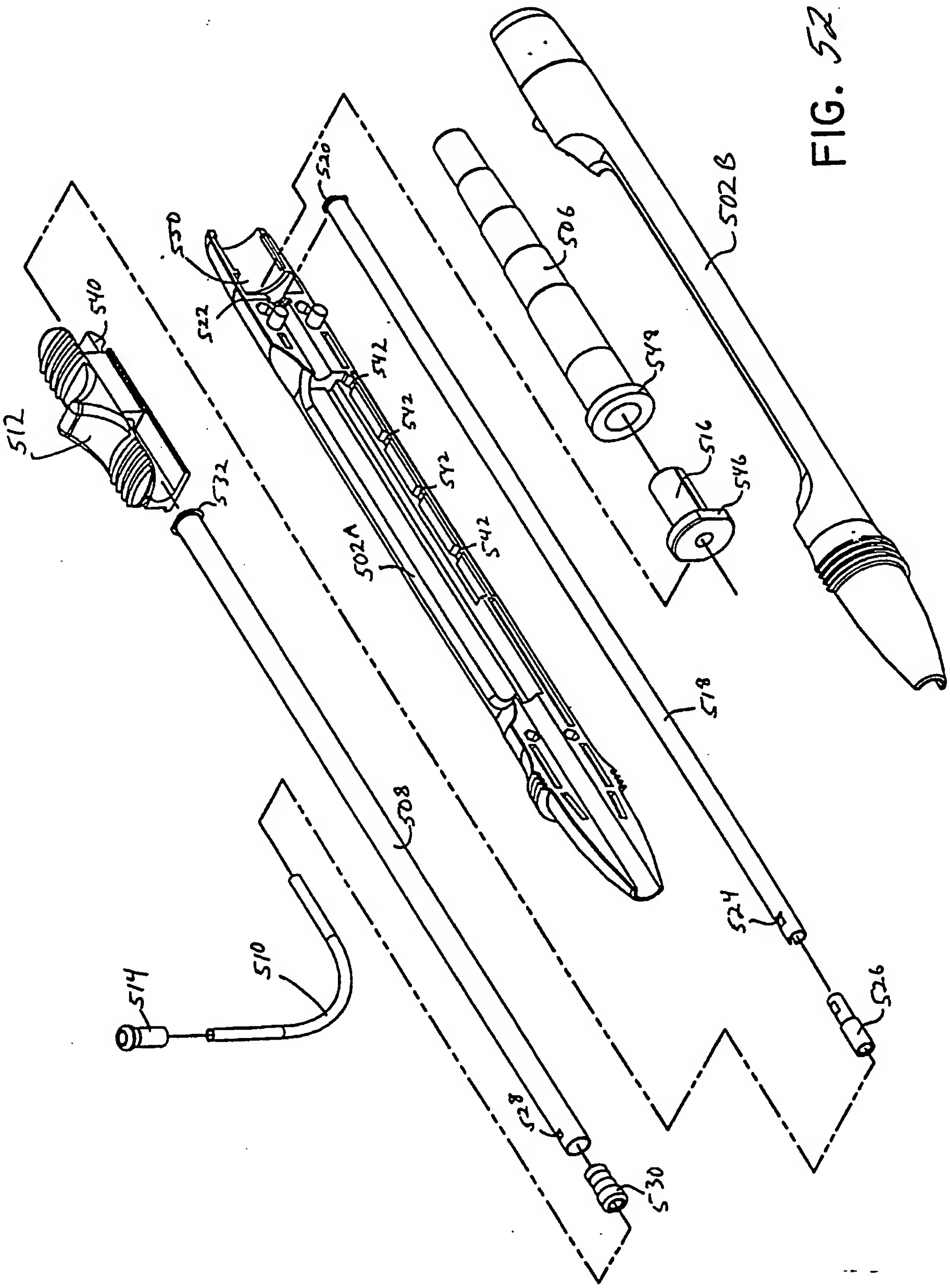
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FIG. 52

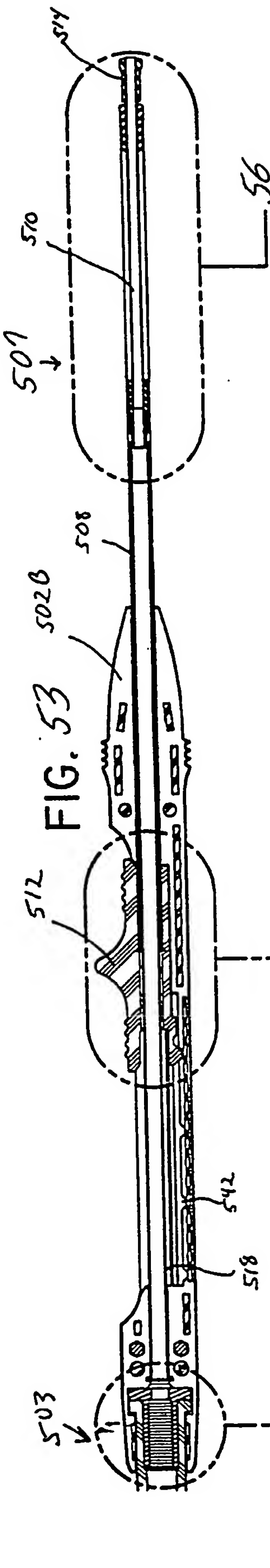

FIG. 53

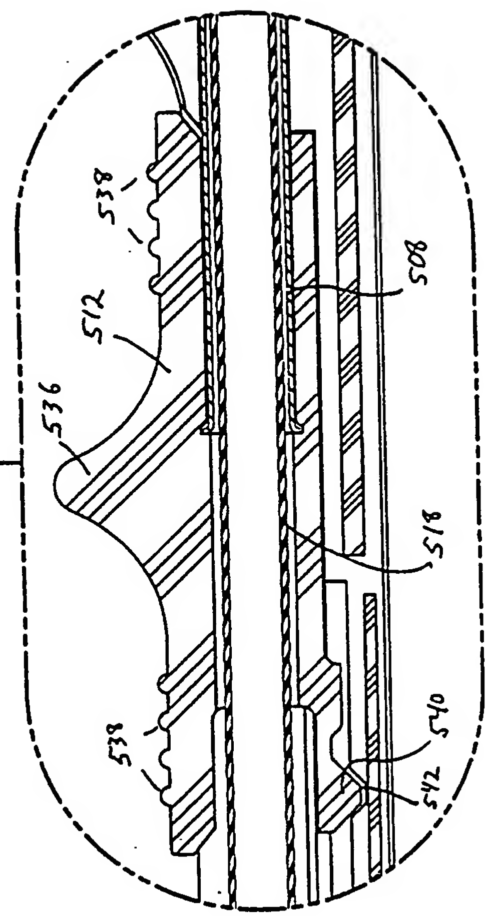

FIG. 55

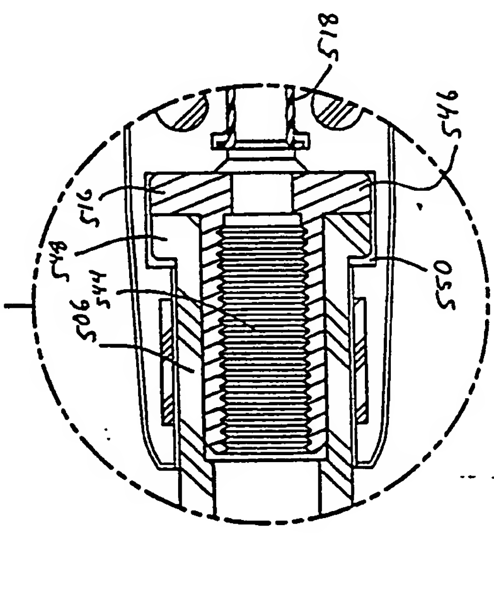

FIG. 54

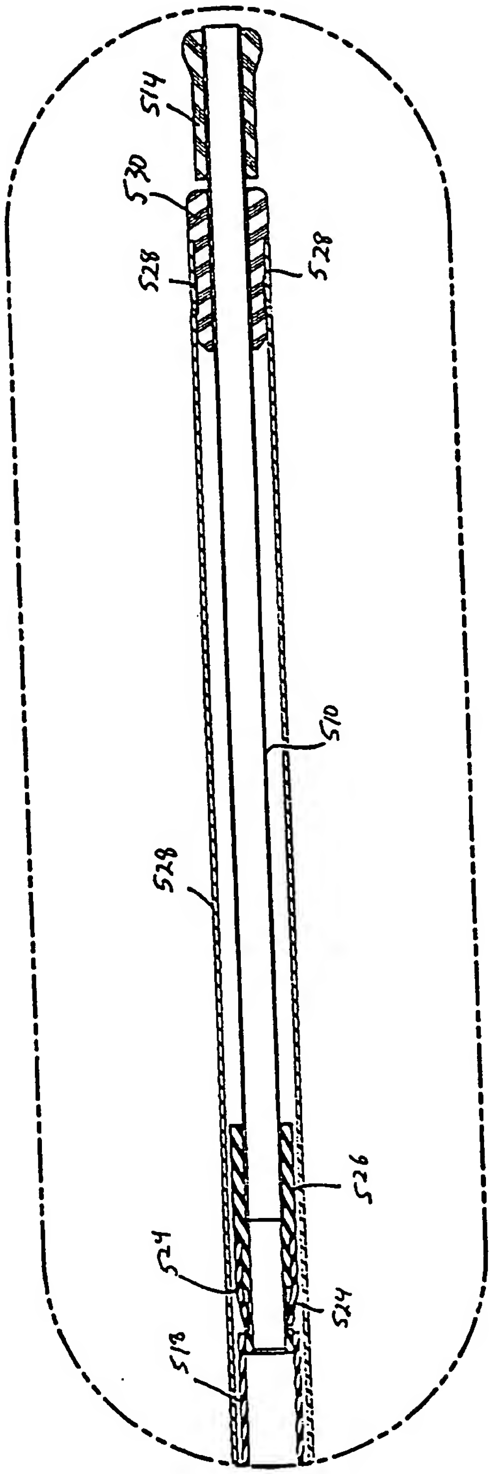

FIG. 56

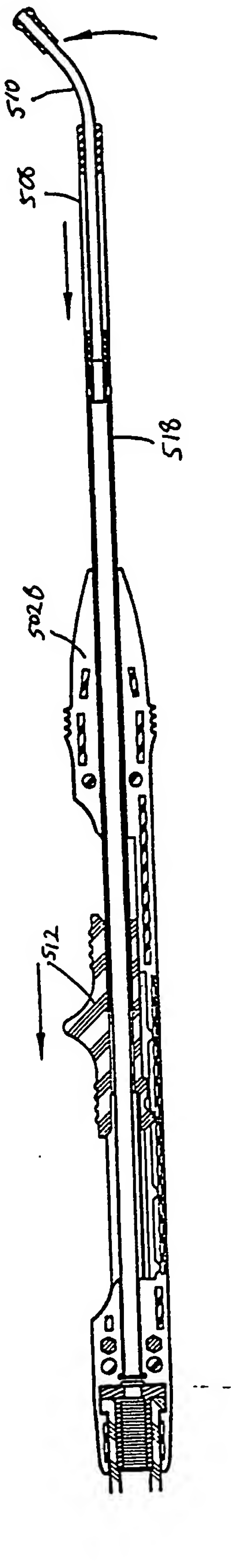

FIG. 57

42/45

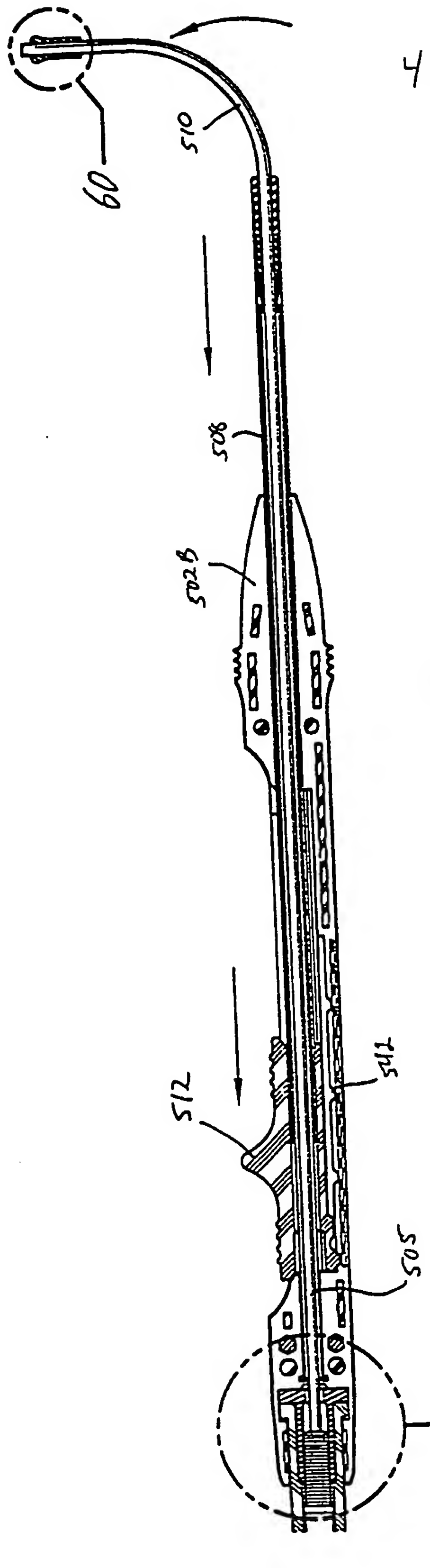

FIG. 58

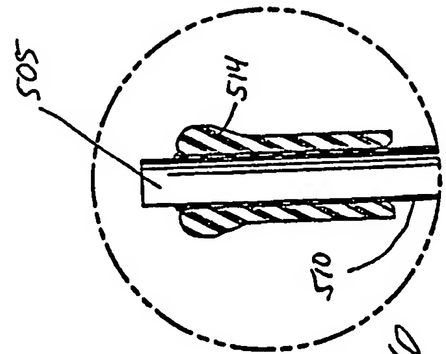

FIG. 60

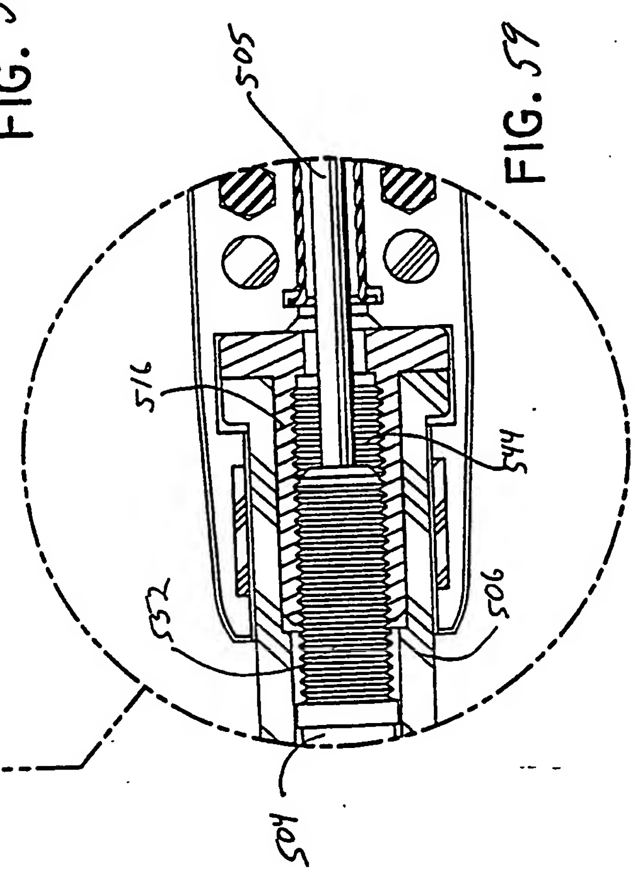

FIG. 59

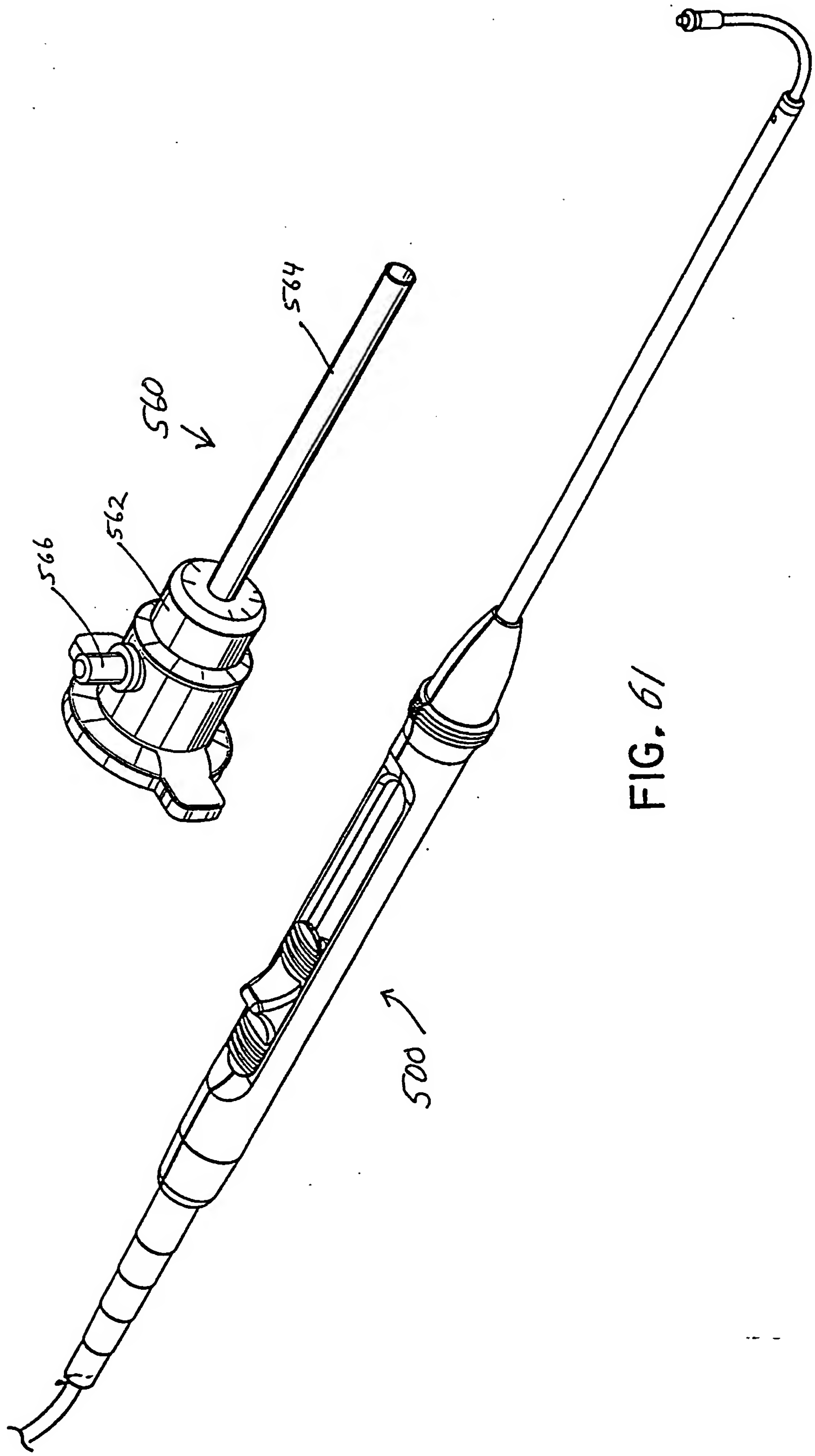

FIG. 61

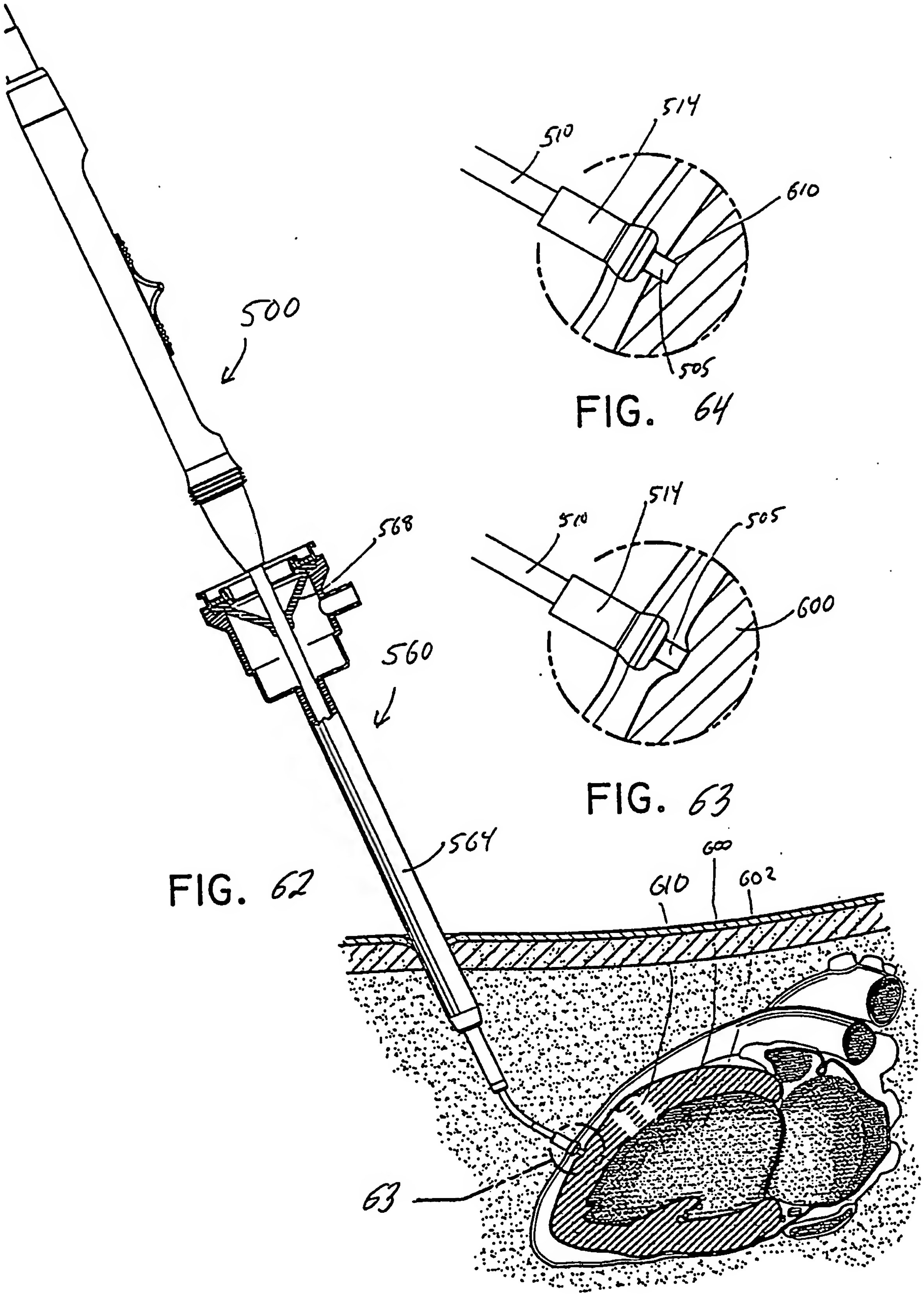
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FIG. 64
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FIG. 63
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FIG. 62

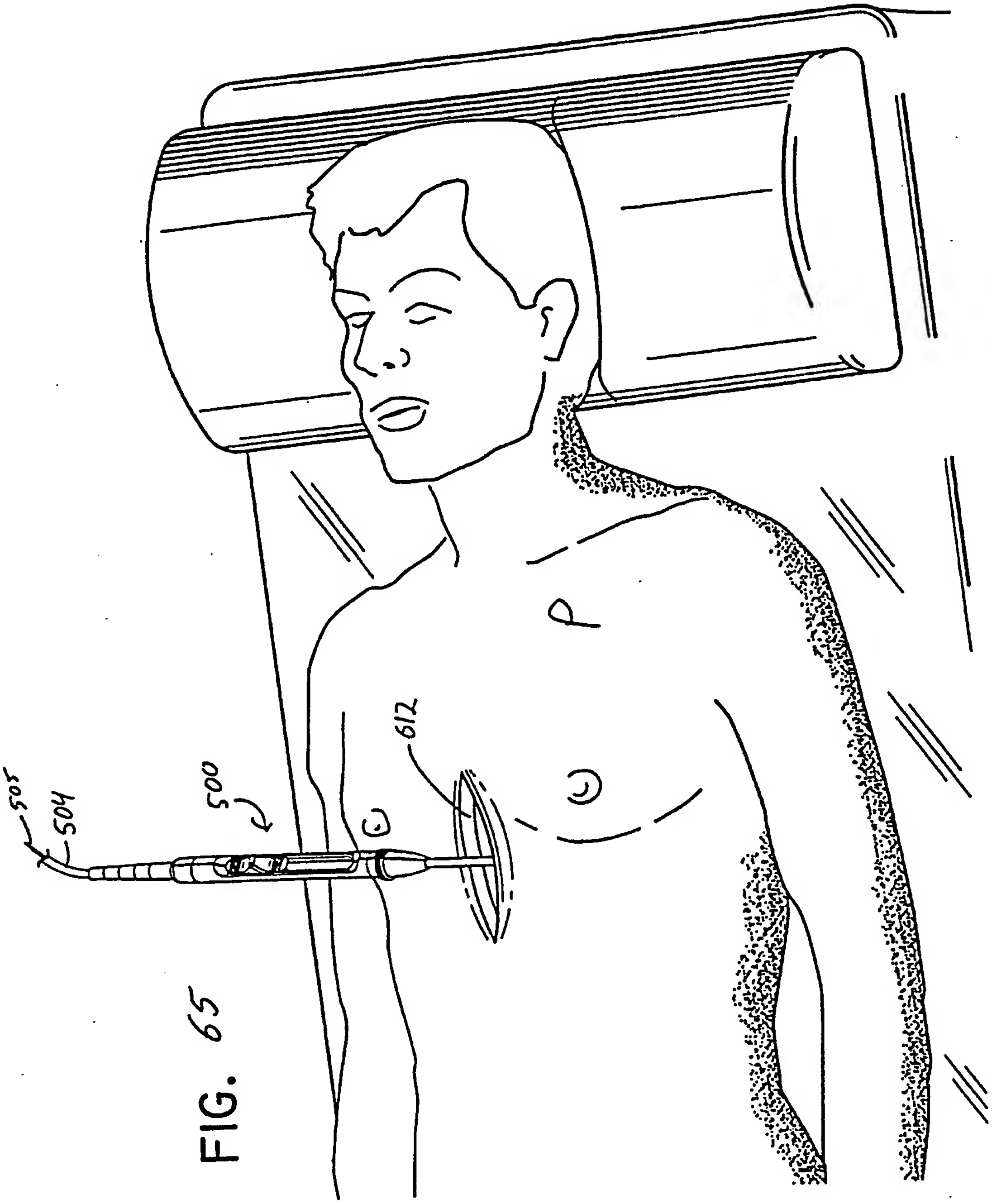

FIG. 65

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